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Best ICD option for patients with no pacing indications

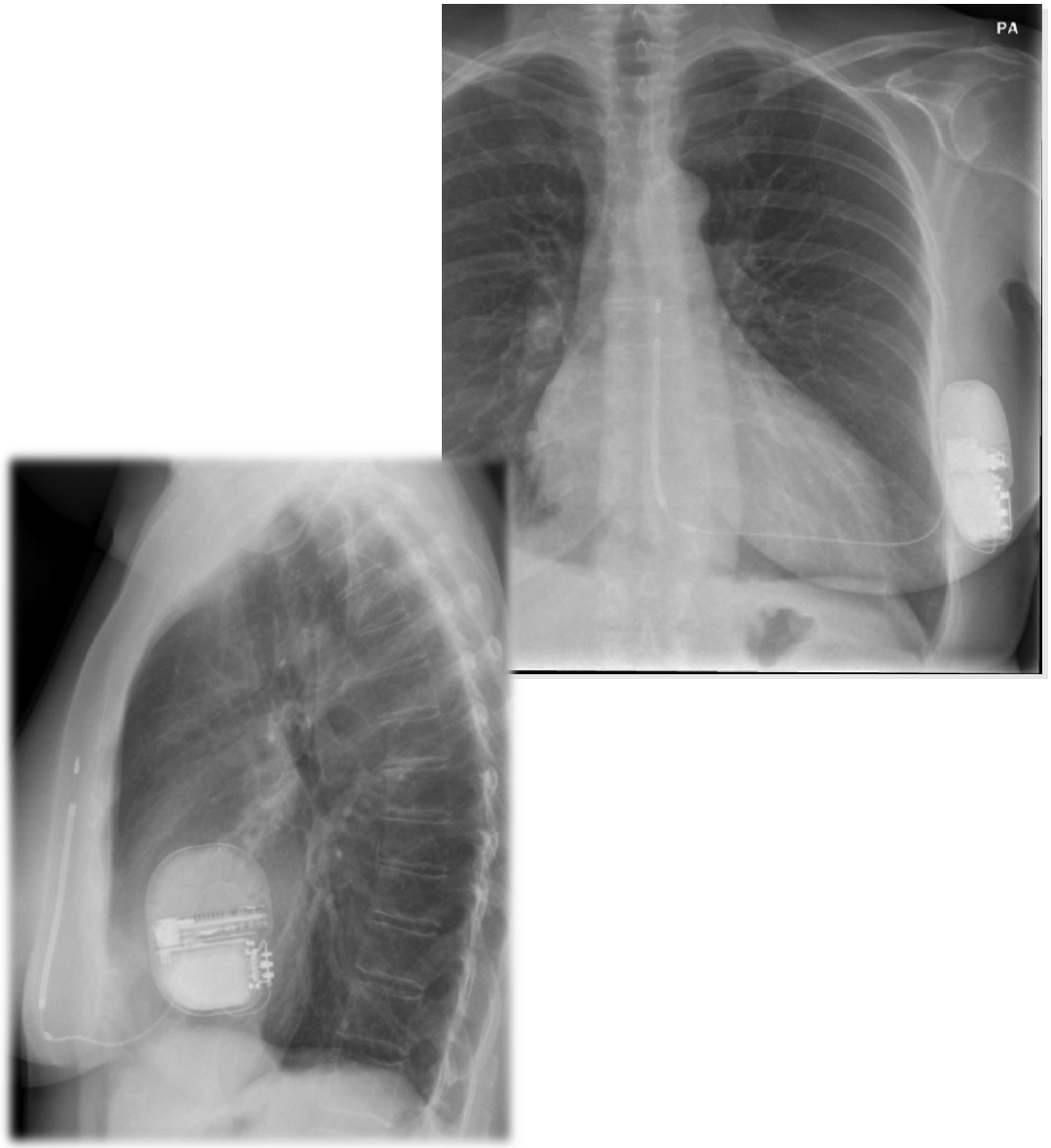
Totally Subcutaneous ICD

Prof Ali Oto,MD,FESC,FACC,FAHA,FSCAI,FHRS

Ankara

Totally subcutaneous ICD (S-ICD) is designed to afford the same life-saving benefit of the conventional TV-ICDs while avoiding the shortcomings of the TV-leads and to simplify the implant techniques and hence expand the use of ICDs in clinical practice.

Commercially available after receiving CE mark in 2009, and its use increased significantly after its FDA approval in 2012.



Current Cardiology Reviews, 2019; 15: 1 45

Limitations of TV-ICD's

Potential Complications

- Localized pocket or wound infection or systemic infection,
- A vascular access related complication such as pneumothorax, and venous thrombosis,
- Lead related complications such as dislodgement, malfunction, perforation and venous obstruction.

Limitations

Transvenous leads placement may not be feasible in certain patients like those with venous anomaly or occlusion, or with the presence of intracardiac shunts.

Problems related to lead extractions

Transvenous leads extraction, when needed, is associated with considerable morbidity & mortality and requires significant skills and costs.

Current Cardiology Reviews, 2019; 15: 1 45

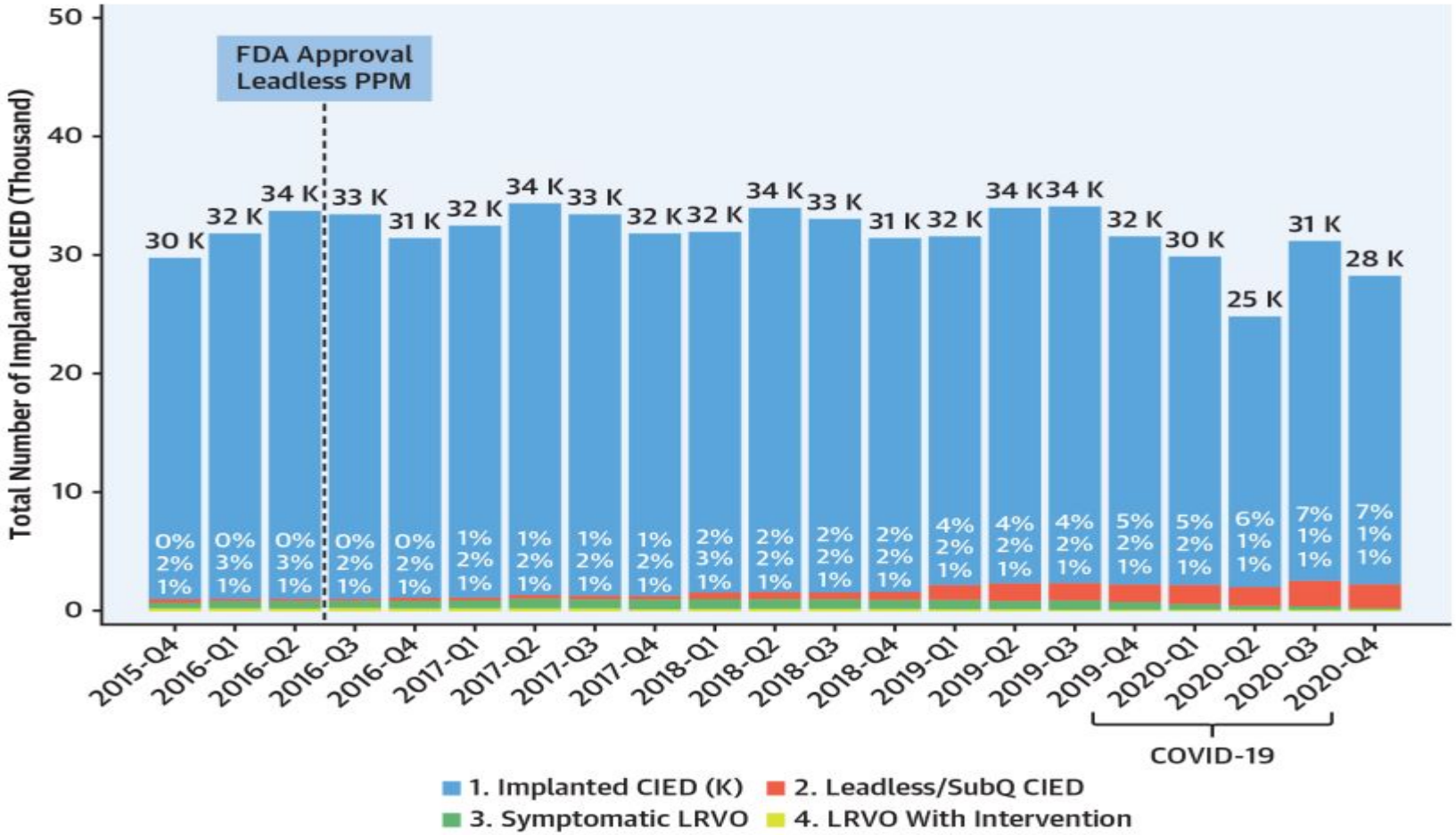
Symptomatic Device Lead-Related Venous Obstruction

- 649,524 patients who underwent CIED implant,
- 28,214 developed LRVO, with 5.0% cumulative incidence
- Maximum follow-up of 5.2 years.
- Independent predictors of LRVO
  - CIEDs with >1 lead (HR: 1.09; 95% CI: 1.07-1.15),
  - Chronic kidney disease (HR: 1.17; 95% CI: 1.14-1.20),
  - Malignancies (HR: 1.23; 95% CI: 1.20-1.27).
- Most patients with LRVO (85.2%) were managed conservatively.
- Among 4,186 (14.8%) patients undergoing intervention, 74.0% underwent CIED extraction and 26.0% percutaneous revascularization.

90% of the patients did not receive another CIED after extraction, with low use (2.2%) of leadless pacemakers.

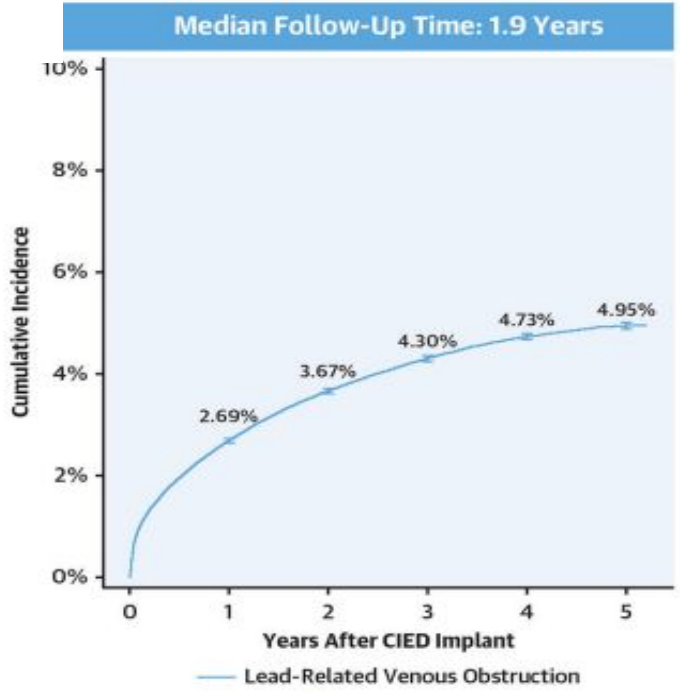
J Am Coll Cardiol. 2023 June 20; 81(24): 2328–2340

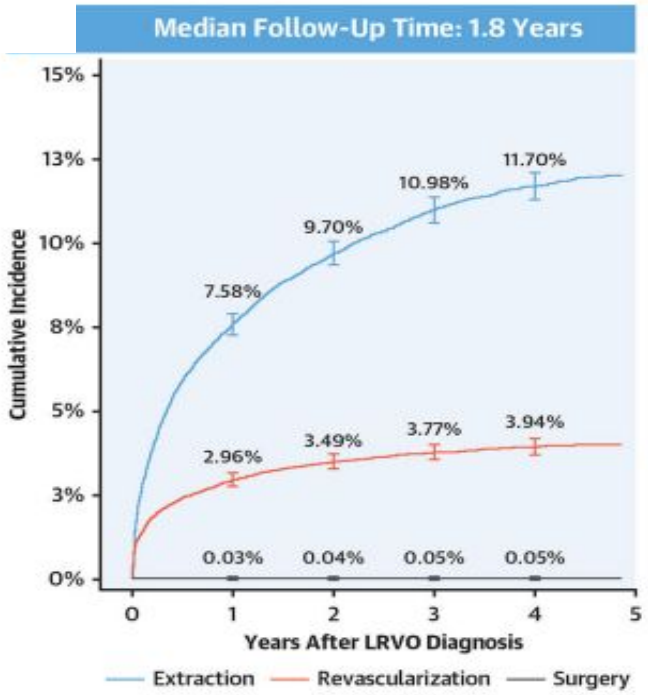
Prevalence LRVO-Related Interventions as a Proportion of CIED Volume

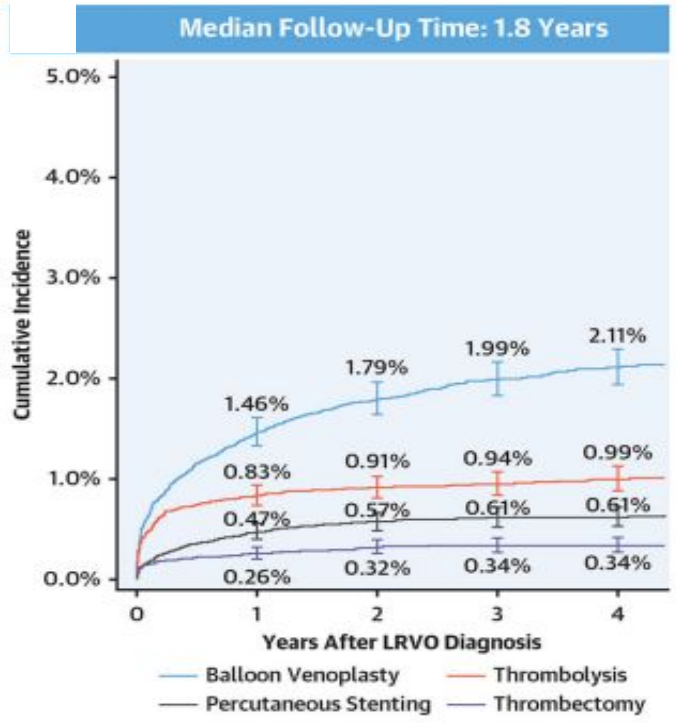


J Am Coll Cardiol. 2023 June 20; 81(24): 2328–2340

Cumulative Incidence Functions of LRVO and LRVO-Related Interventions

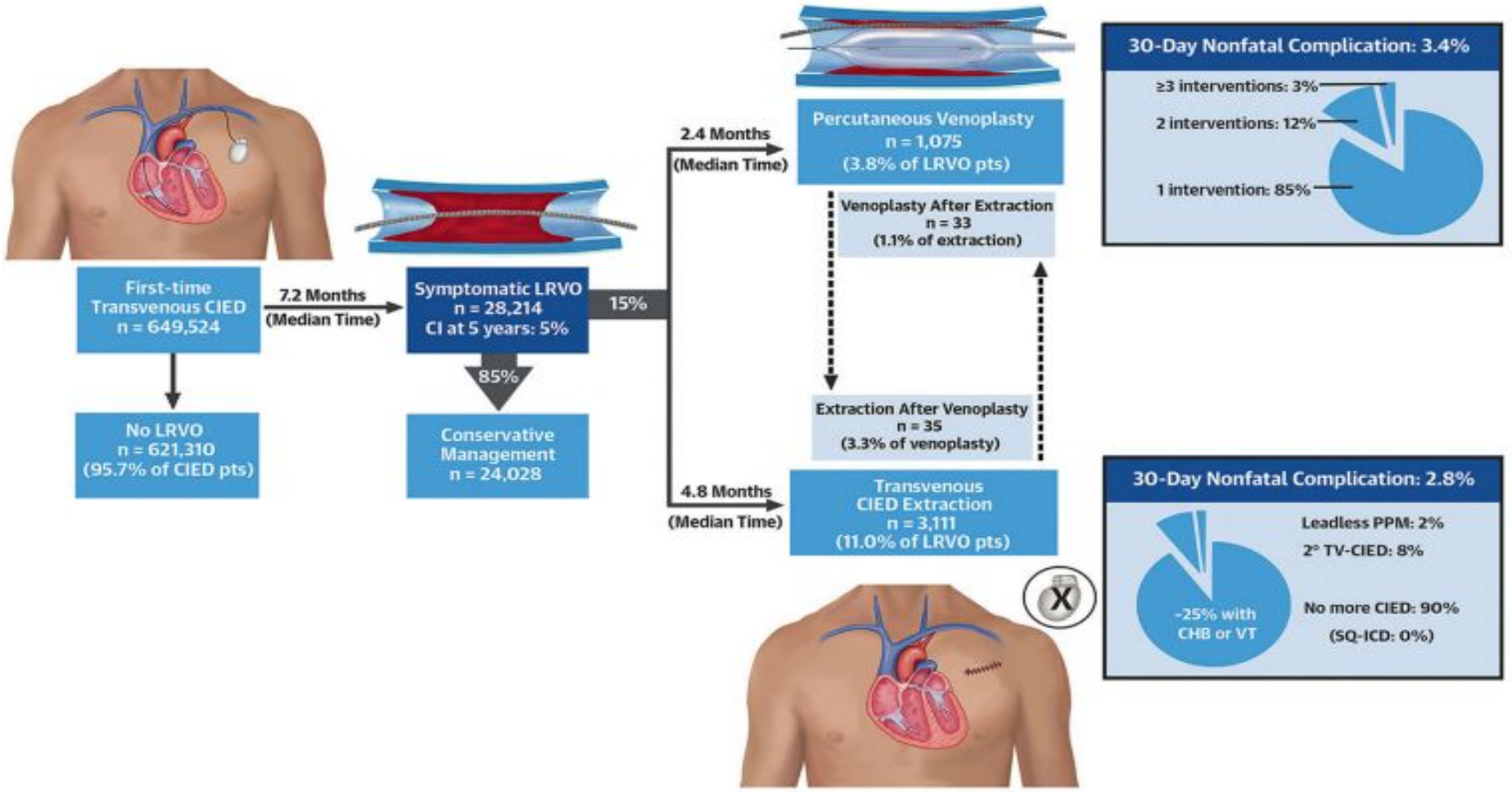






J Am Coll Cardiol. 2023 June 20; 81(24): 2328–2340

Natural History of Lead-Related Venous Obstruction



J Am Coll Cardiol. 2023 June 20; 81(24): 2328–2340

Mortality after TV ICD Lead Extraction Due to Infection

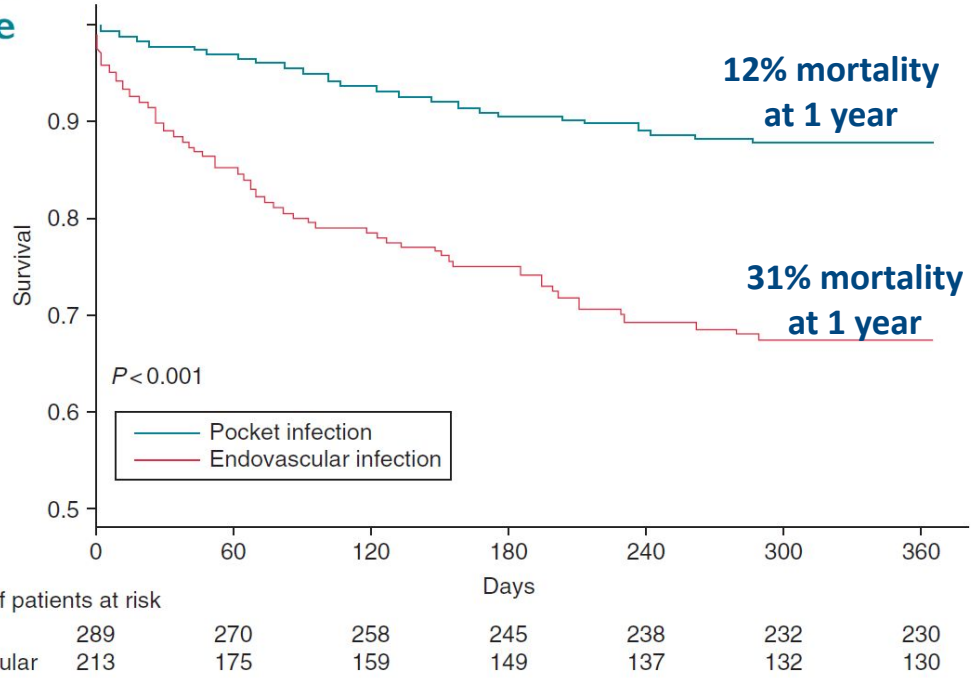
Europace (2014) **16**, 1490–1495
doi:10.1093/europace/euu147

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

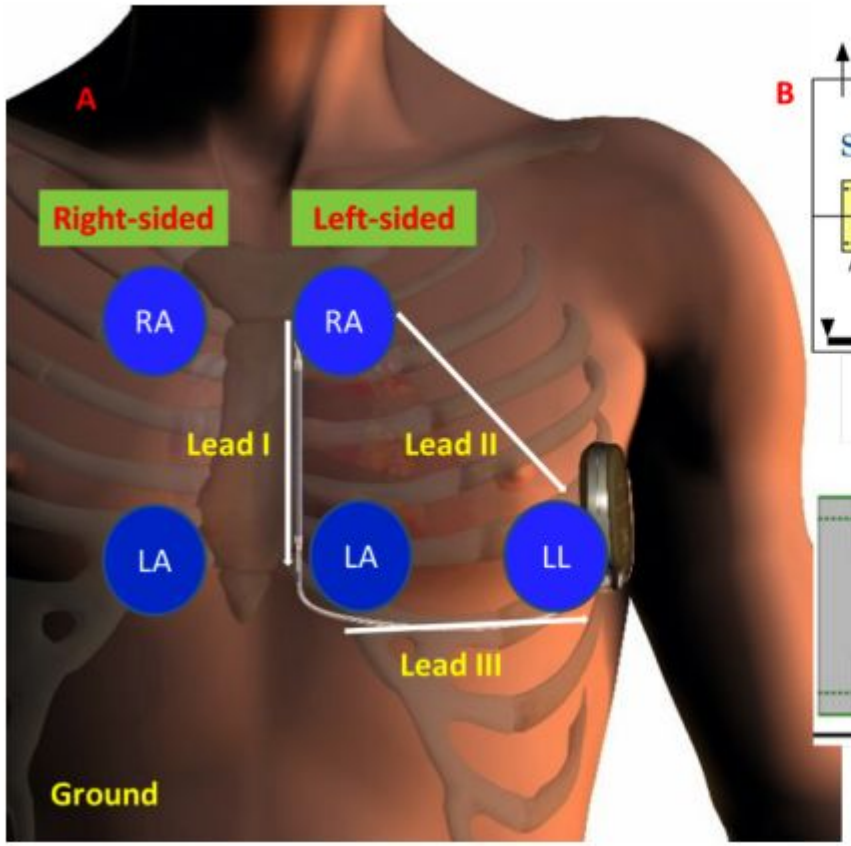
- All patients with CIED infections who underwent device and lead removal at the Cleveland Clinic from January 2002 through 2008
- 2476 patients, 2.6% incidence of infection
- 20.3% mortality within the first year
  - Pocket infection 12% mortality
  - Endovascular infection 31% mortality

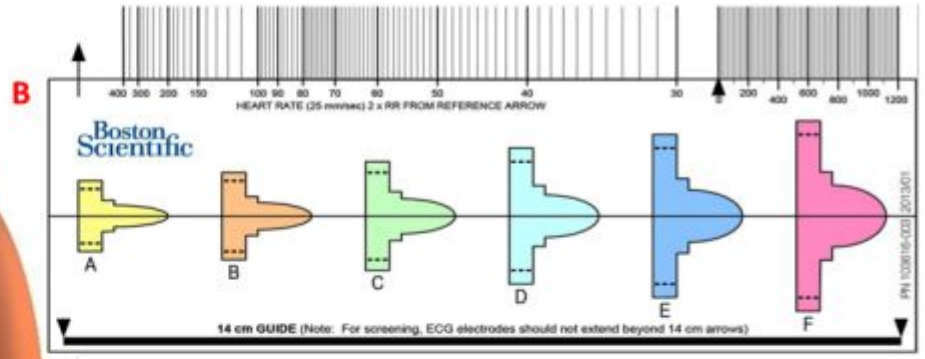
TV-ICD patients with pocket infection and endovascular infection following TV-ICD system removal

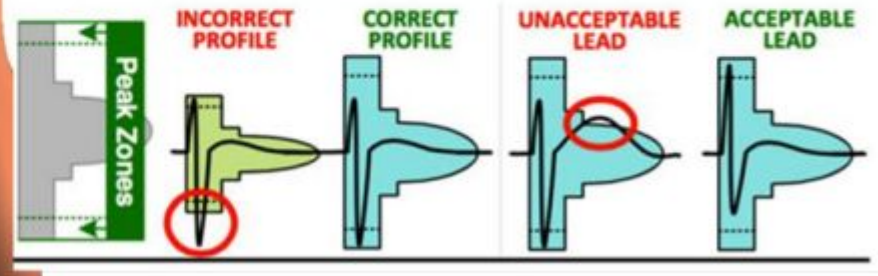


Tarakji KG, Wazni OM, Harb S, Hsu A, Saliba W, Wilkoff BL. *Europace* 2014;16:1490-5.

Location of the surface ECG electrodes positions during screening for eligibility for S-ICD in conventional left and right parasternal configurations and ECG screening tool with examples of acceptable and unacceptable QRS complexes and T-waves







Current Cardiology Reviews, 2019; 15: 1 45

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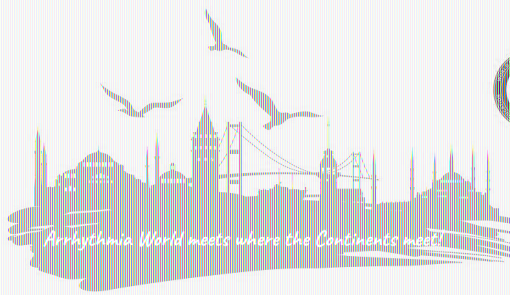

ESC European Society of Cardiology
European Heart Journal (2022) 43, 2037–2050
https://doi.org/10.1093/eurheartj/ehab921
CLINICAL RESEARCH
Clinical trials

Subcutaneous implantable cardioverter-defibrillators: long-term results of the EFFORTLESS study

5-year outcomes of EFFORTLESS registry patients with early generation subcutaneous implantable cardioverter-defibrillator (S-ICD) devices

- S-ICD implantation in 984 patients with diverse diagnoses (28% female, 48+17 years, body mass index 27+ 6 kg/m2 , ejection fraction 43 +18%).
- Median follow-up 5.1 years (interquartile range 4.7–5.5 years).
- All-cause mortality 9.3% (95% confidence interval 7.2–11.3%) at 5 years;
- 703 patients remained in follow-up on study completion, 171 withdrew including 87 (8.8%) with device explanted, and 65 (6.6%) lost to follow-up. Of the explants, only 20 (2.0%) patients needed a transvenous device for pacing indications.
- First and final shock efficacy for discrete ventricular arrhythmias was consistent at 90% and 98%, respectively, with storm episode final shock efficacy at 95.2%. Time to therapy remained unaltered.
- 1- and 5-year complication rates were 8.9% and 15.2%, respectively. There were no structural lead failures. Inappropriate shock rates at 1 and 5 years were 8.7% and 16.9%, respectively.

Self-terminating inappropriately sensed episodes predicted late IAS. Predictors of late AS included self-terminating appropriately sensed episodes and earlier AS.

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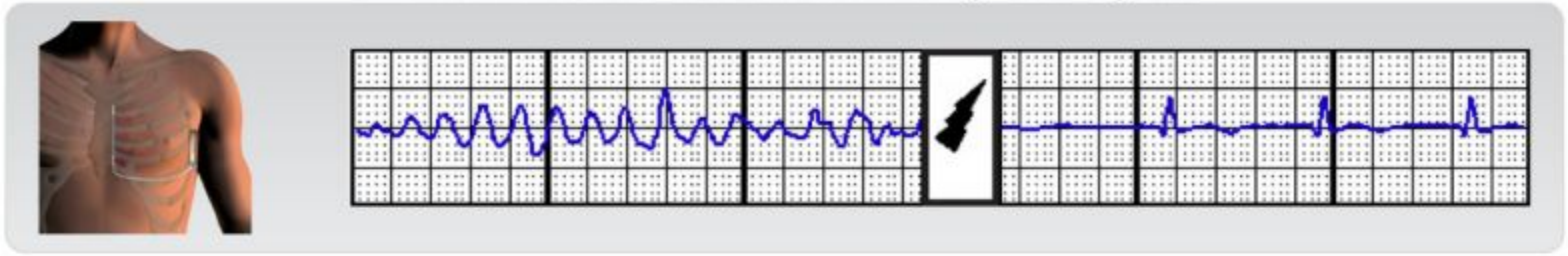
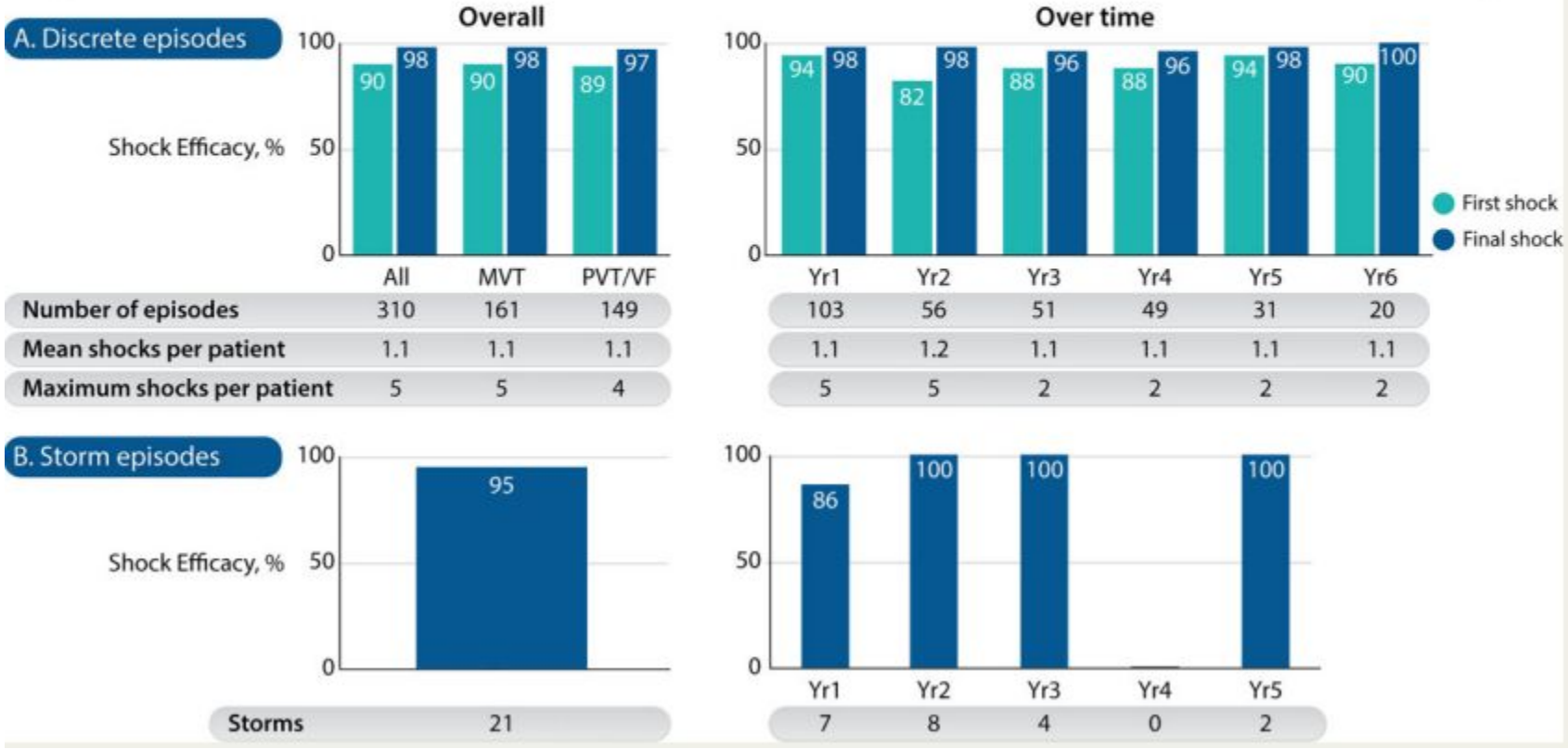
CLINICAL RESEARCH
Clinical trials

Subcutaneous implantable cardioverter-defibrillators: long-term results of the EFFORTLESS study

Conclusion In this diverse S-ICD registry population, spontaneous shock efficacy was consistently high over 5 years. Very few patients underwent S-ICD replacement with a transvenous device for pacing indications. Treated and self-terminating arrhythmic episodes predict future shock events, which should encourage more personalized device optimization

Maintenance of S-ICD Shock Efficacy over 5 years





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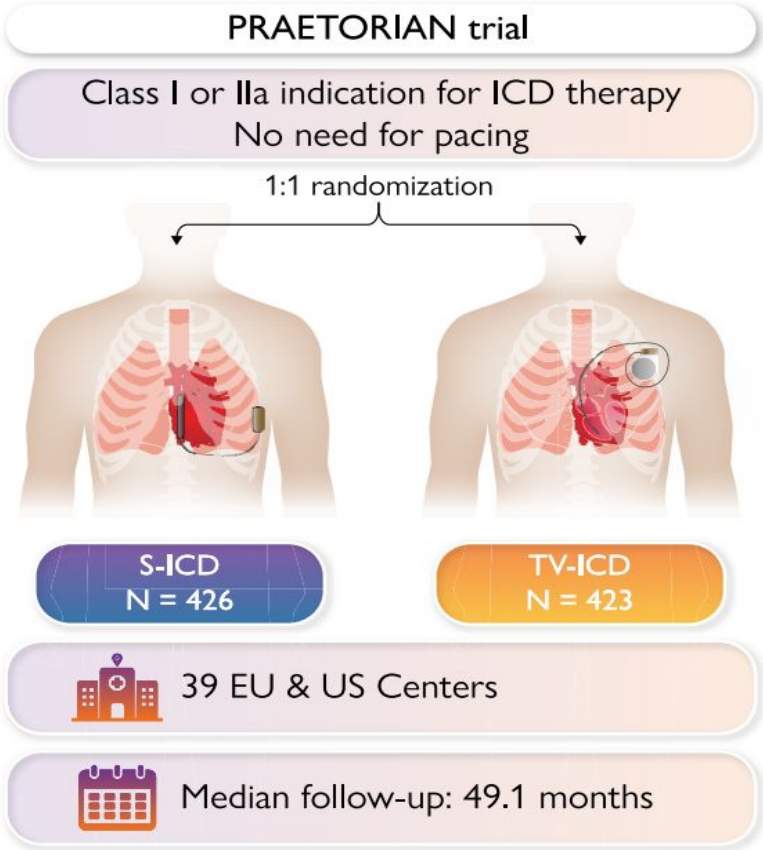
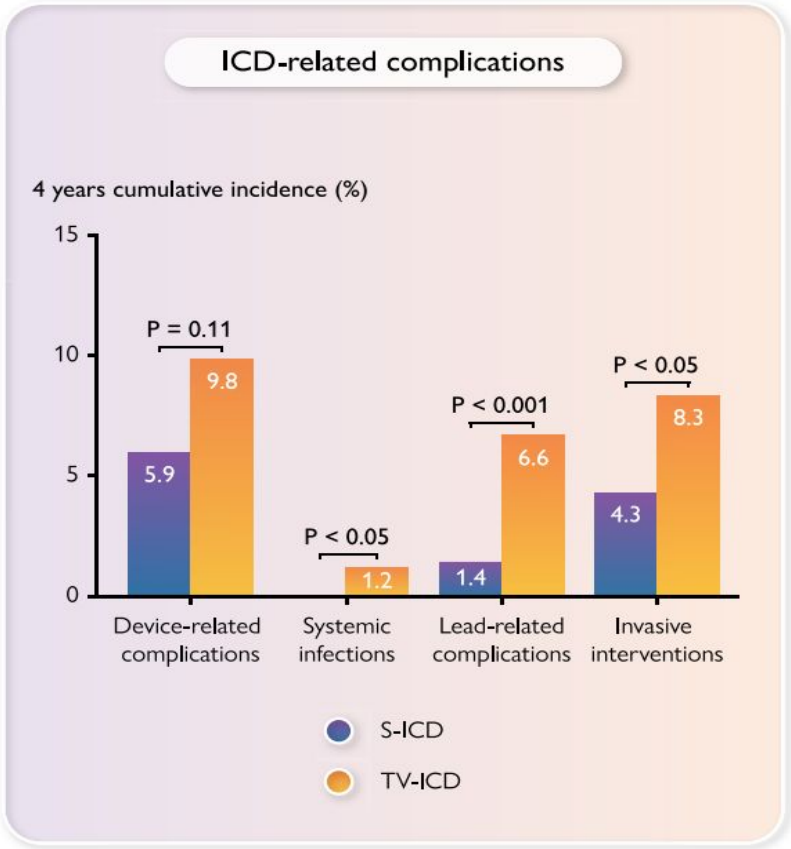
European Heart Journal (2022) 43, 4872–4883
https://doi.org/10.1093/eurheartj/ehac496

FASTTRACK CLINICAL RESEARCH
Arrhythmias

Device-related complications in subcutaneous versus transvenous ICD: a secondary analysis of the PRAETORIAN trial

The PRAETORIAN trial demonstrated that the S-ICD is non-inferior to the TV-ICD with regard to the combined primary endpoint of inappropriate shocks and complications. This prespecified secondary analysis evaluates all complications in the PRAETORIAN trial. (An international, multicentre, randomized trial)





- **Conclusion** This secondary analysis shows that lead-related complications and systemic infections are more prevalent in the TV-ICD group compared with the S-ICD group. In addition, complications in the TV-ICD group were more severe as they required significantly more invasive interventions. This data contributes to shared decision-making in clinical practice

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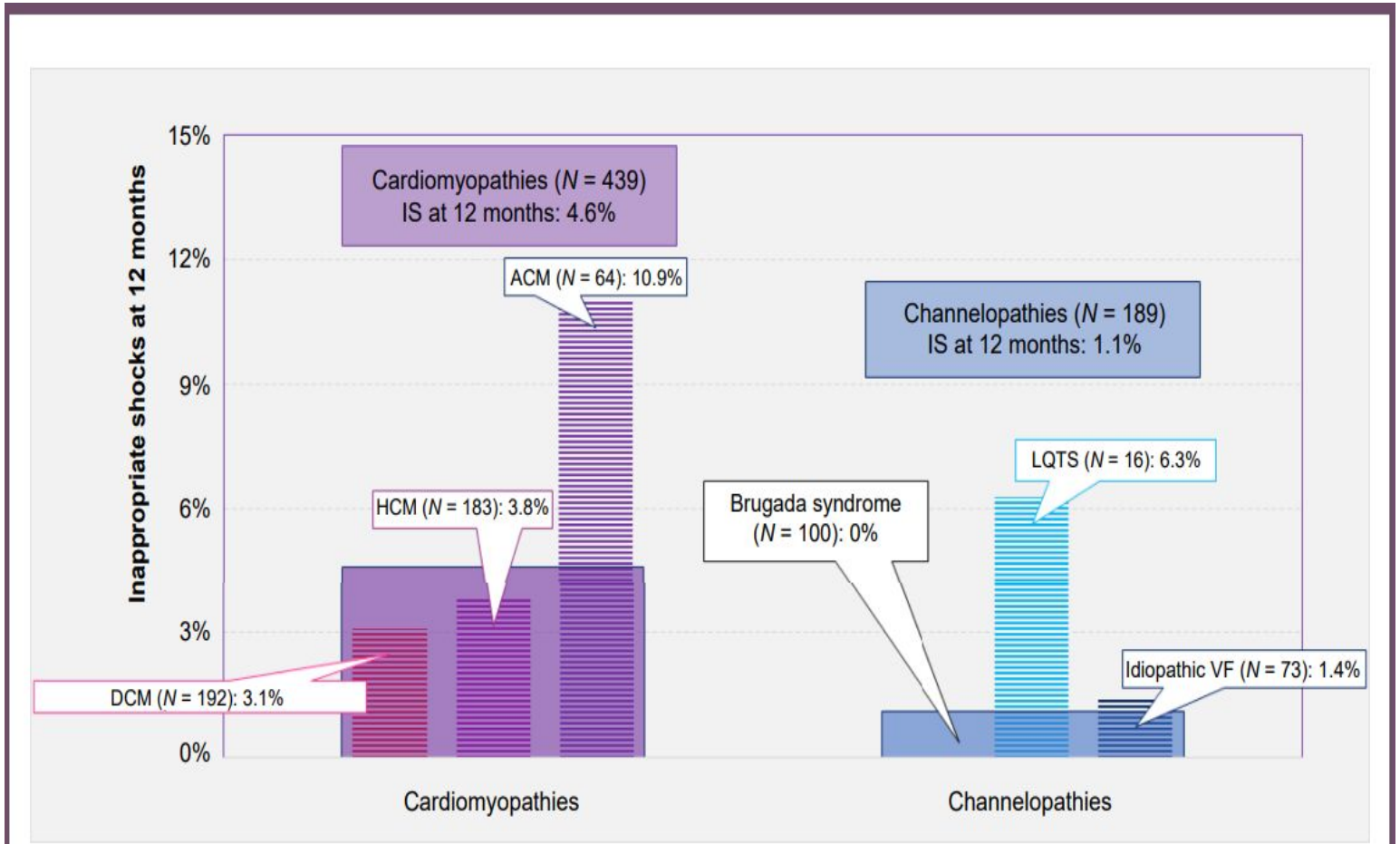
Europace (2023) 25, 1–11
https://doi.org/10.1093/europace/euad239
CLINICAL RESEARCH

Modern subcutaneous implantable defibrillator therapy in patients with cardiomyopathies and channelopathies: data from a large multicentre registry



- 1338 consecutive patients with cardiomyopathies and channelopathies who had undergone implantation of a modern S-ICD .
- The rate of IS at 12 months was 4.6% [95% confidence interval (CI): 2.8–6.9] in patients with cardiomyopathies and 1.1% (95% CI: 0.1–3.8) in patients with channelopathies (P = 0.032).
- The rate of appropriate shocks at 12 months was 2.3% (95% CI: 1.1–4.1) in patients with cardiomyopathies and 2.1% (95% CI: 0.6–5.3) in patients with channelopathies (P = 1.0).
- The rate of device-related complications was 0.9% (95% CI: 0.3–2.3) and 3.2% (95% CI: 1.2–6.8), respectively
- Over a long-term follow-up, the need for pacing is low, occurring in 0.8% of the overall population

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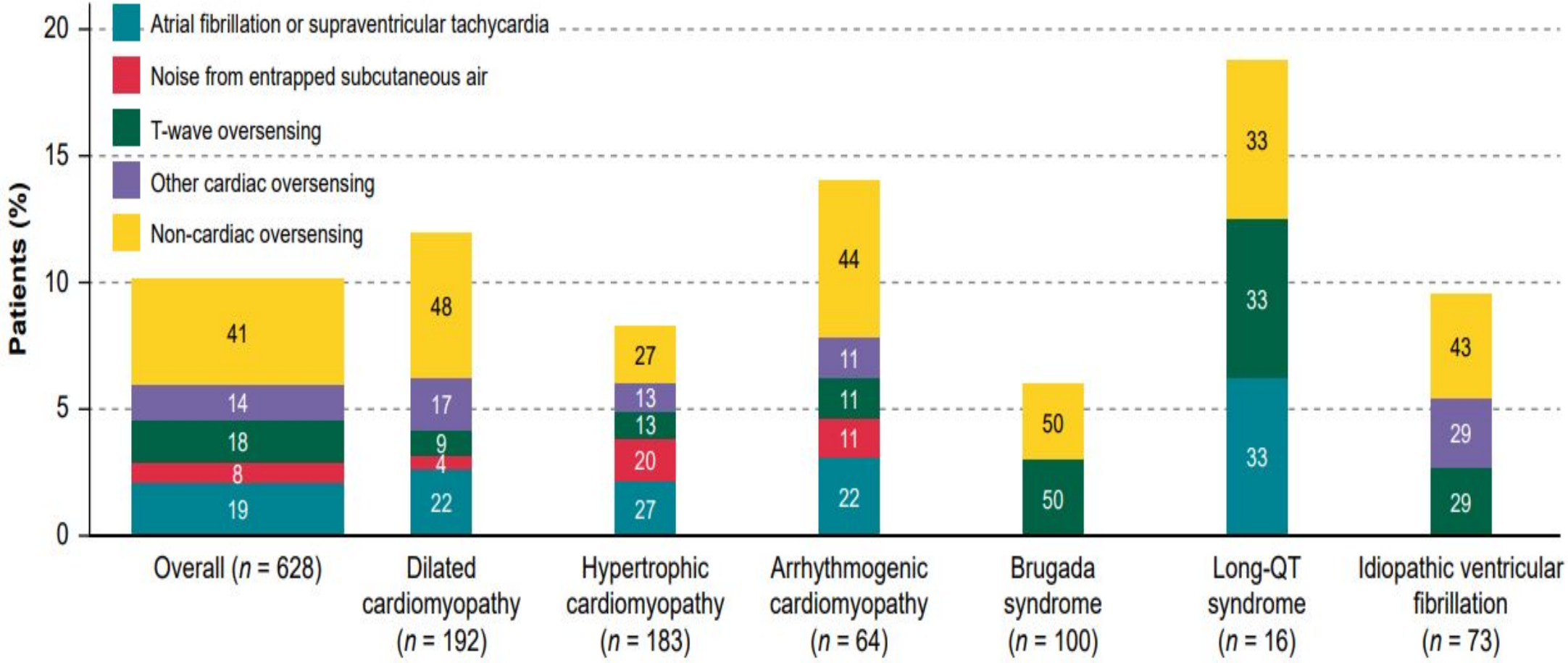
Modern subcutaneous implantable defibrillator therapy in patients with cardiomyopathies and channelopathies: data from a large multicentre registry



Causes of inappropriate shocks reported during follow-up and distribution according to the type of cardiomyopathy and channelopathy

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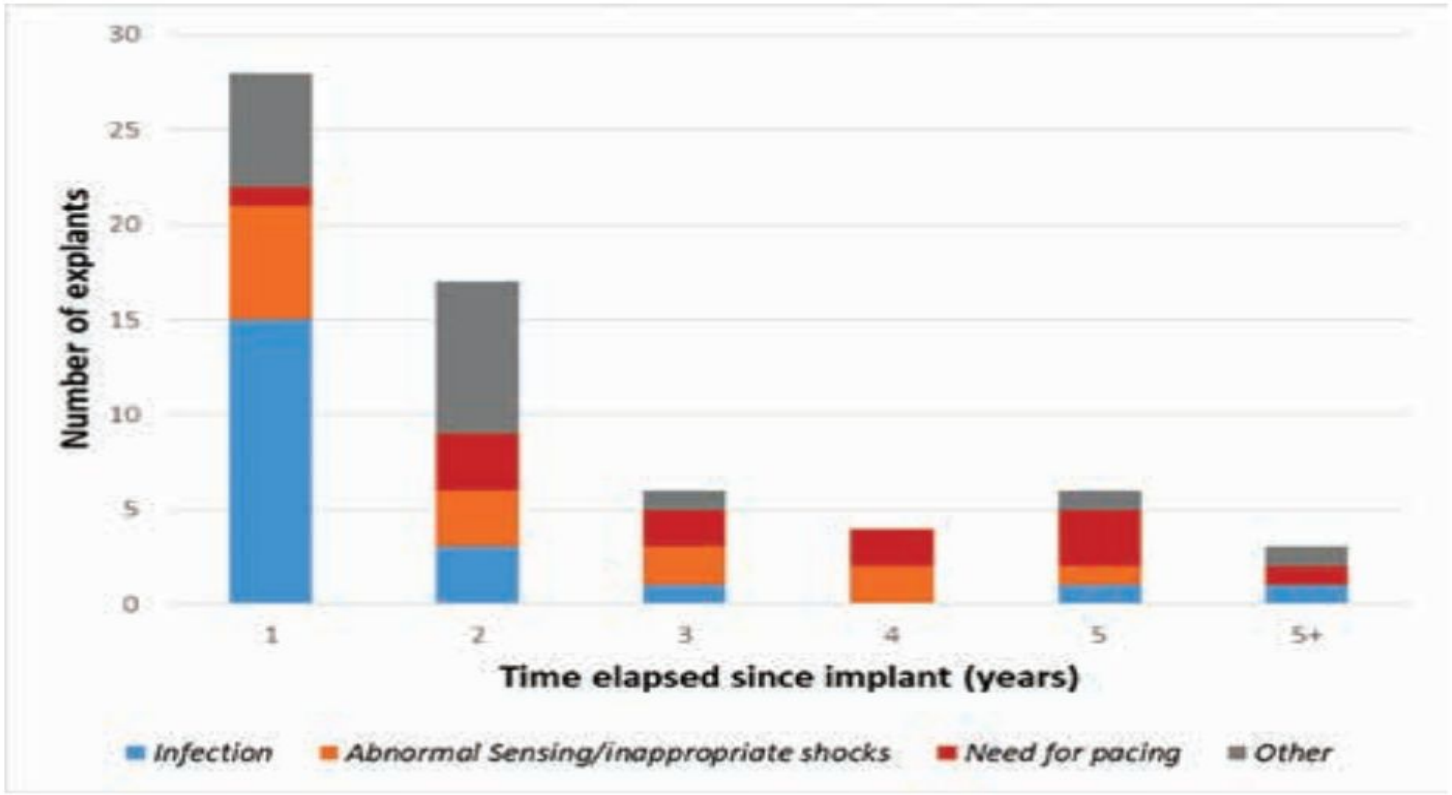
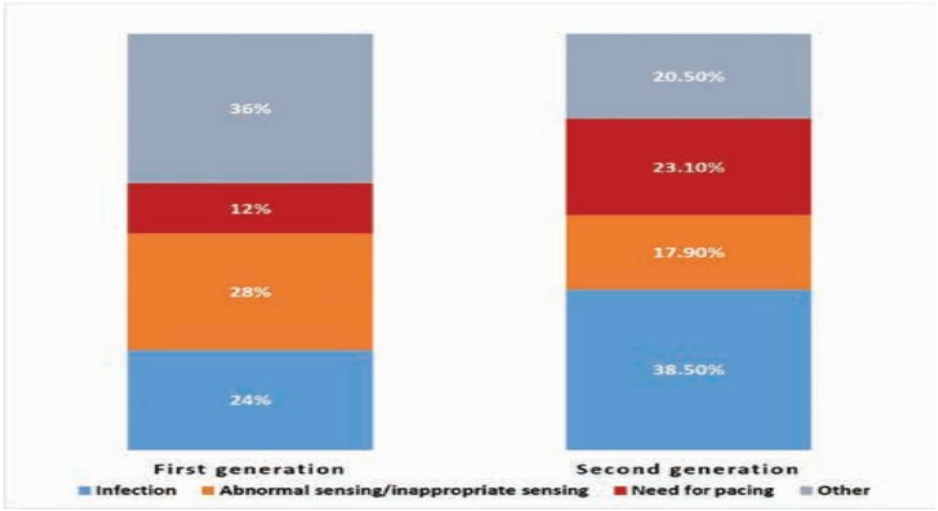
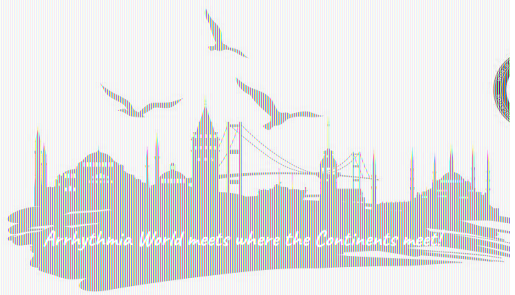
S-ICD Explantation (n = 64) Indications	N (%)
Infection	21 (32.8%)
Inappropriate shocks	12 (18.8%)
Oversen[illegible] (without shocks)	1 (1.6%)
Underse[illegible]g VF	1 (1.6%)
Unsucc[illegible]defibrillation	2 (3.1%)
Need for pacing	
Cardiac resynchronization	10 (15.6%)
Sinus node dysfunction	2 (3.1%)
Patient discomfort	3 (4.7%)
Heart transplant/LVAD	7 (10.9%)
Other	
Need for MRI	1 (1.6%)
Impedance high at PG change	1 (1.6%)
Premature battery depletion	1 (1.6%)
Failed DFT testing at PG change	1 (1.6%)
No data available	1 (1.6%)





The Journal of Innovations in Cardiac Rhythm Management, April 2022



The ATLAS Trial

- **544 pts were ECG screened and 503 (92.5%) randomized: 251 to S-ICD and 252 to TV-ICD.**
- **Mean follow up 2.5 ± 1.1 years.**
- **Mean age 49.0 ± 11.5 years, and 22.5% had a prior cardiac arrest.**
- **Major lead complications occurred in 1 (0.4%) patient with S-ICD and 12 (4.8%) with TV-ICD (odds ratio, 0.08; 95% CI, 0.00 to 0.55; p=0.003). (92 % reduction).**
- **No statistically significant differences in the rate of inappropriate shocks, or the rate of failed appropriate clinical shocks. The rate of inappropriate shocks showed a trend toward a higher risk with S-ICDs versus TV-ICDs (6.4 versus 2.8%), not statistically significant**

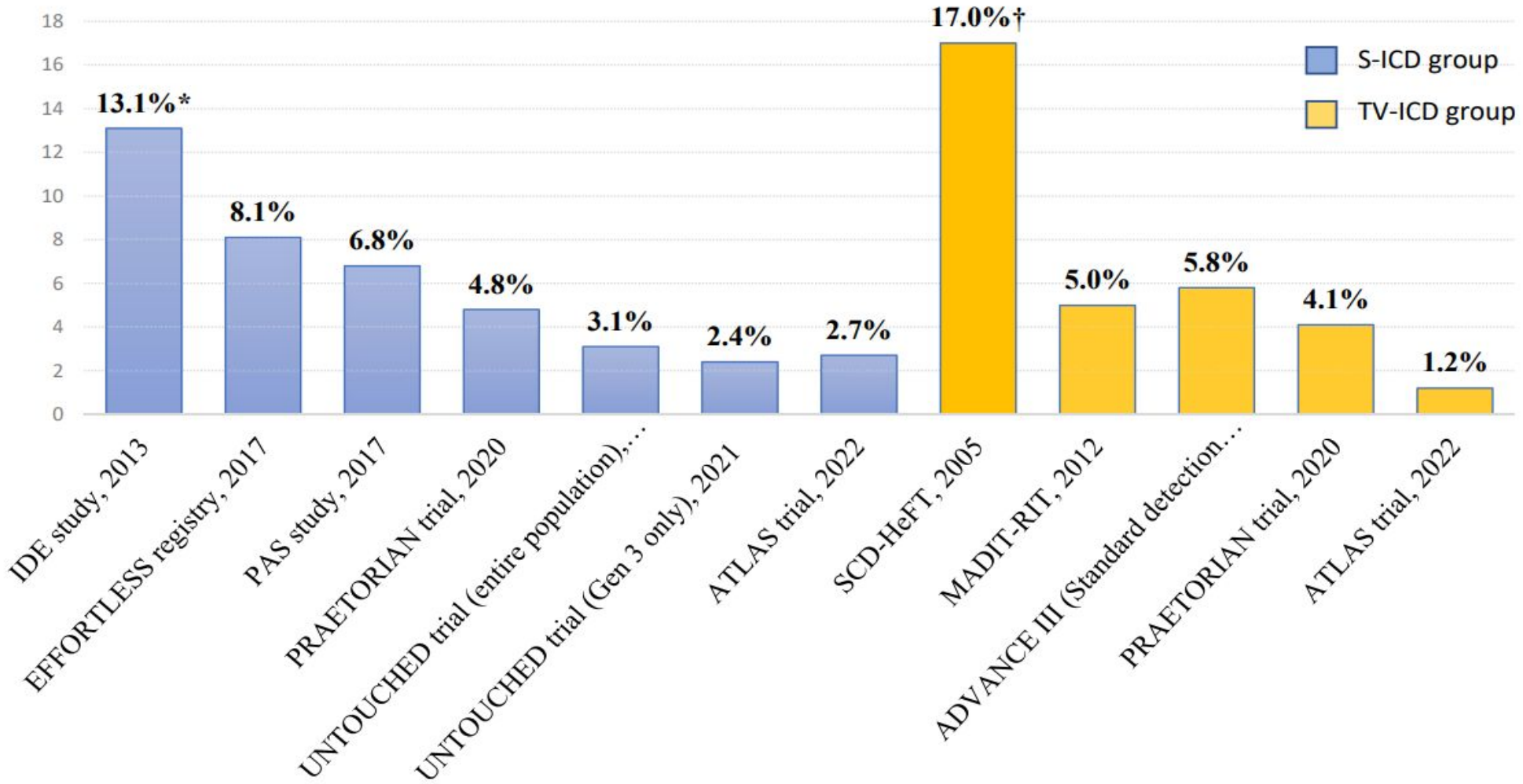
Conclusion

S-ICD is superior to TV-ICD regarding serious lead-related complications and can be considered as an alternative to the TV-ICD, particularly in patients at increased risk for lead-related complications.

Follow-up of ATLAS participants is ongoing, to increase the statistical power to assess the comparative rates of inappropriate shocks and failed appropriate shocks, as well as the impact of ICD type on tricuspid insufficiency and heart failure

the ATLAS trial. Heart Rhythm 2022;19:1223–5

Annual inappropriate shocks rates across different ICD studies.



(Heart Rhythm O2 2022;3:589–596)

S-ICD Lead Extraction

Systematic Review

- 30 studies , with 207 patients who underwent SLE.
- The majority of SLEs were performed for non-infective causes (59.90%).
- Infection of the device (affecting either the lead or the pocket) was the cause of SLE in 38.65% of cases.
- SLEs were performed using manual traction or with the aid of a tool designed for transvenous lead extraction (TLE), including either a rotational or nonpowered mechanical dilator sheath.

Conclusions: SLE is performed mainly for non-infective causes. Techniques vary greatly across different studies. Dedicated tools for SLE might be developed in the future and standard approaches should be defined. In the meantime, authors are encouraged to share their experience and data to further refine the existing variegated approaches.

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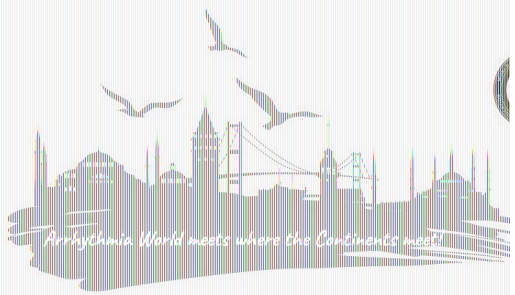

Subcutaneous implantable cardioverter-defibrillator: a systematic review of comparative effectiveness and safety

Sarah Wolf, Gregor Götz , Bernhard Wernly and Claudia Wild

- One RCT, a post hoc analysis of the RCT (n = 849) and four controlled observational studies (n = 7149) were included.
- After 4 years, the RCT showed that S-ICD was non-inferior to TV-ICD regarding the composite endpoint of inappropriate shocks and device-related complications (68 [15.1%] vs. 68 [15.7%], hazard ratio [HR] 0.99, 95% confidence interval [CI] [0.71, 1.39], non-inferiority margin 1.45, P = 0.001). The RCT
- Two observational studies reported statistically significantly fewer lead complications in S-ICD patients (after 4 years: 1.4% vs. 6.6%, HR 0.24, 95% CI [0.10, 0.54]; after 3 years: 0.3% vs. 2.3%, P = 0.03; and after 5 years: 0.8% vs. 11.5%, P = 0.03).
- Identified evidence about appropriate and inappropriate shocks was inconclusive: The RCT detected statistically significantly more appropriate shocks in patients with S-ICD (83 [19.2%] vs. 57 [11.5%], HR 1.52, 95% CI [1.08, 2.12], P = 0.02), whereas one observational study showed a statistically significantly lower rate in the S-ICD group (9.9%, 95% CI [7.0, 13.9], vs. 13.9%, 95% CI [10.8, 17.8], P = 0.003).

ESC Heart Failure 2023; 10: 808–823

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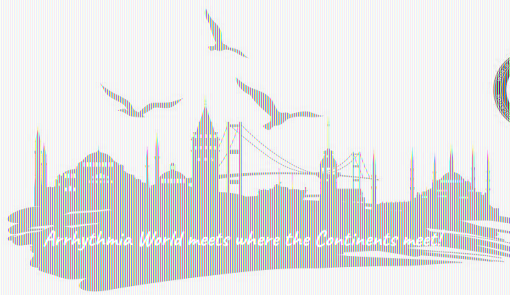

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- **Regarding inappropriate shocks, one observational study reported statistically significantly higher rates in the S-ICD cohort (11.9% vs. 7.5%, P = 0.007), whereas the RCT and two other observational studies did not detect a statistically significant difference between the treatment groups (P > 0.05).**
- **None of the included studies showed a statistically significant difference in overall mortality and shock efficacy between patients with S-ICD and TV-ICD (P > 0.05).**
- **The available evidence is insufficient to show the superiority of S-ICD compared with TV-ICD, hindering the widespread use of the technology. Results of the recently completed ATLAS trial are to be awaited, and the anticipated role of the S-ICD needs to be clearly formulated. Keywords Implantable cardioverter-defibrillator; ICD; Subcutaneous; Transvenous; Sudden cardiac death; Evidence-based medicine**

ESC Heart Failure 2023; 10: 808–823

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Efficacy and Complications of Subcutaneous versus Conventional Cardioverter Defibrillators: A Systematic Review and Meta-Analysis

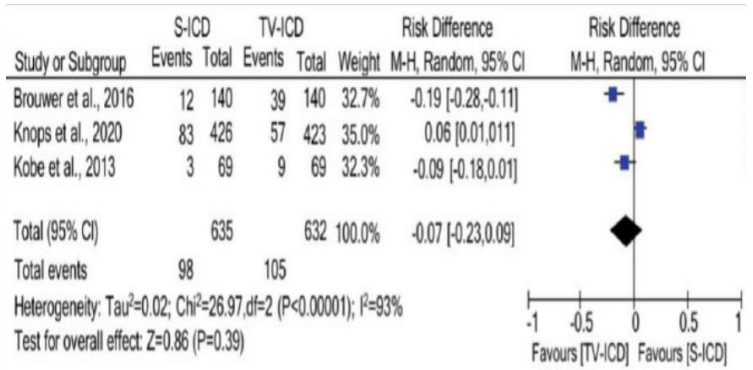
Five Studies , n=2111

The most frequent complication in the subcutaneous device group was infection, followed by hematoma formation and electrode migration.

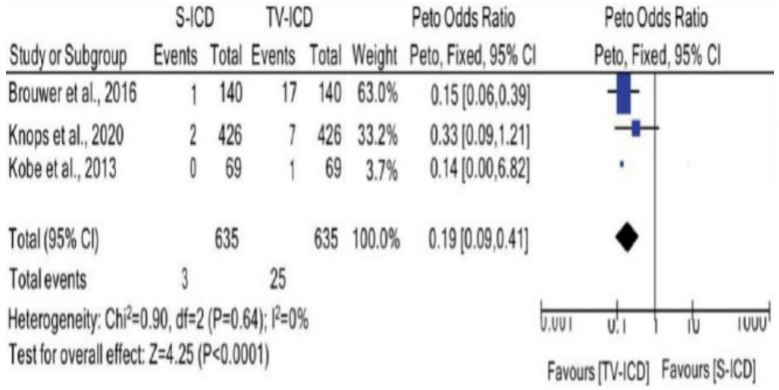
For the transvenous device, the most frequent complications were electrode migration and infection.

Total rates of appropriate shocks were 9.04% and 20.47% in the subcutaneous and transvenous device groups, respectively, whereas inappropriate shocks to the subcutaneous and transvenous device groups were 11,3% and 10,7%, respectively.

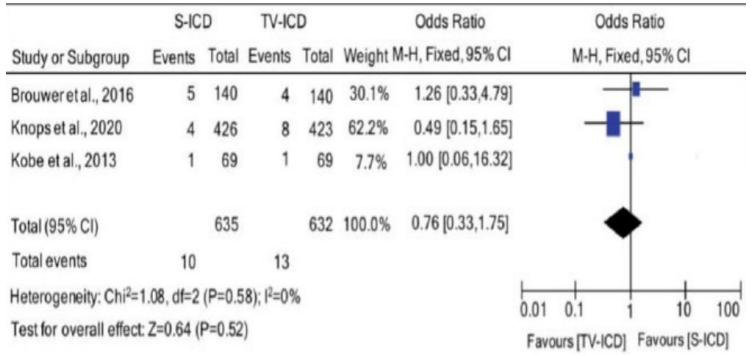
Current Cardiology Reviews, 2022, 18, e081221198647



Inappropriate shock



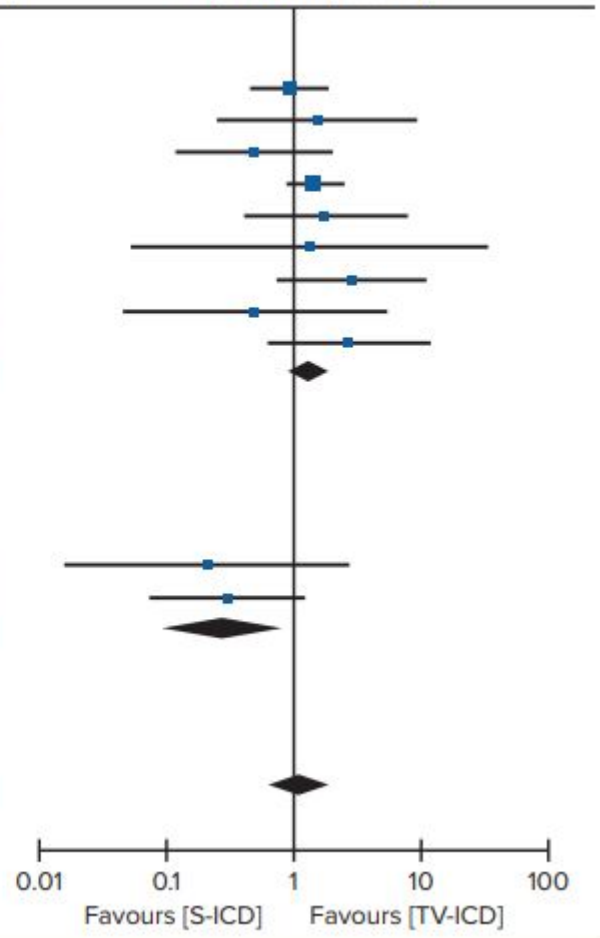
Lead migration



Infection

Meta-analysis Findings for Inappropriate Shocks

Study or Subgroup	S-ICD Events	S-ICD Total	TV-ICD Events	TV-ICD Total	Weight	OR M-H, Random [95% CI]
3.7.1 Adult						
Boveda, 2018	0	31	0	30		Not estimable
Brouwer, 2016	20	140	22	140	22.5%	0.89 [0.46–1.72]
Brouwer, 2018	3	391	2	391	4.7%	1.50 [0.25–9.05]
Honarbakhsh, 2017	3	69	6	69	7.1%	0.48 [0.11–1.99]
Knops, 2020	41	426	29	423	30.1%	1.45 [0.88–2.38]
Kobe, 2013	5	69	3	69	6.7%	1.72 [0.39–7.49]
Lenarczyk, 2018	0	76	1	307	1.6%	1.34 [0.05–33.11]
Liang, 2019	8	86	3	86	7.7%	2.84 [0.73–11.08]
Mithani, 2018	1	91	2	91	2.7%	0.49 [0.04–5.55]
Viani, 2019	5	90	3	139	6.8%	2.67 [0.62–11.45]
Subtotal (95% CI)		**1,469**		**1,746**	**89.9%**	**1.28 [0.91–1.79]**
Total events	86		71			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 6.28$, df = 8 (p=0.62); $I^2 = 0\%$						
Test for overall effect: Z = 1.44 (p=0.15)						
3.7.2 Pediatric						
Pettit, 2013	1	9	3	8	2.5%	0.21 [0.02–2.60]
Quast, 2018	3	35	11	46	7.7%	0.30 [0.08–1.17]
Subtotal (95% CI)		**44**		**54**	**10.1%**	**0.28 [0.08–0.91]**
Total events	4		14			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.06$, df = 8 (p=0.27); $I^2 = 0\%$						
Test for overall effect: Z = 2.11 (p=0.03)						
Total (95% CI)		**1,513**		**1,800**	**100.0%**	**1.09 [0.73–1.64]**
Total events	90		85			
Heterogeneity: $Tau^2 = 0.08$; $Chi^2 = 12.19$, df = 10 (p=0.27); $I^2 = 18\%$						
Test for overall effect: Z = 0.43 (p=0.66)						
Test for subgroup differences; $Chi^2 = 5.84$, df = 1 (p=0.02); $I^2 = 82.9\%$						



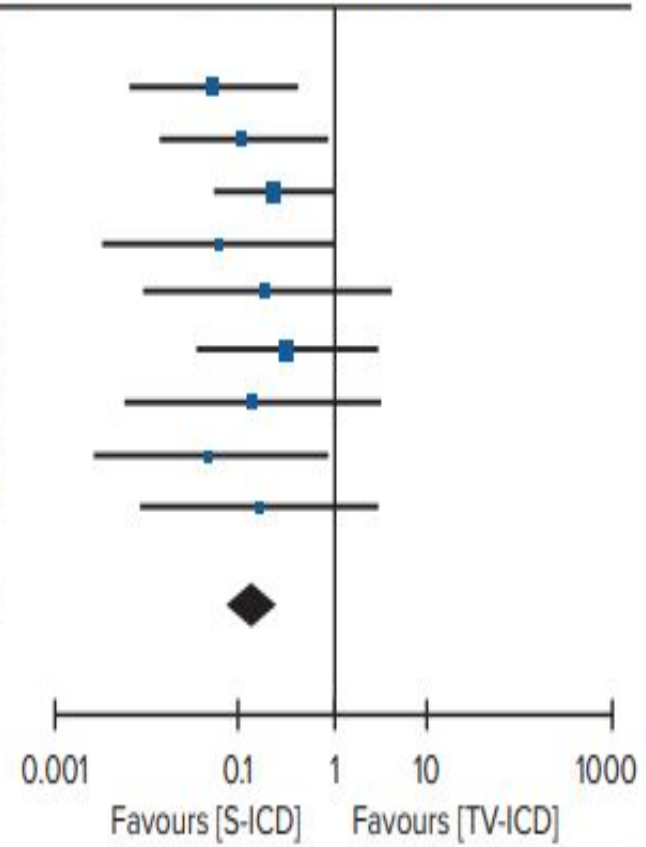
ARRHYTHMIA & ELECTROPHYSIOLOGY REVIEW,2022

Meta-analysis Findings for Lead-related Complicatons

Study or Subgroup	S-ICD Events	S-ICD Total	TV-ICD Events	TV-ICD Total	Weight	OR M-H, Random [95% CI]
Boveda, 2018	0	31	0	31		Not estimable
Brouwer, 2016	1	140	17	140	14.3%	0.05 [0.01–0.40]
Brouwer, 2018	1	391	9	391	13.8%	0.11 [0.01–0.86]
Friedman, 2016	2	1,920	16	3,840	27.3%	0.25 [0.06–1.08]
Honarbakhsh, 2017	0	69	7	69	7.1%	0.06 [0.00–1.07]
Kobe, 2013	0	69	2	69	6.3%	0.19 [0.01–4.12]
Liang, 2019	1	86	3	86	11.3%	0.33 [0.03–3.19]
Petit, 2013	0	9	2	8	5.8%	0.14 [0.01–3.34]
Quast, 2018	0	35	10	46	7.2%	0.05 [0.00–0.87]
Viani, 2019	0	90	4	139	6.9%	0.17 [0.01–3.13]
Total (95% CI)		**2,840**		**4,819**	**100.0%**	**0.14 [0.06–0.29]**
Total events	5		70			

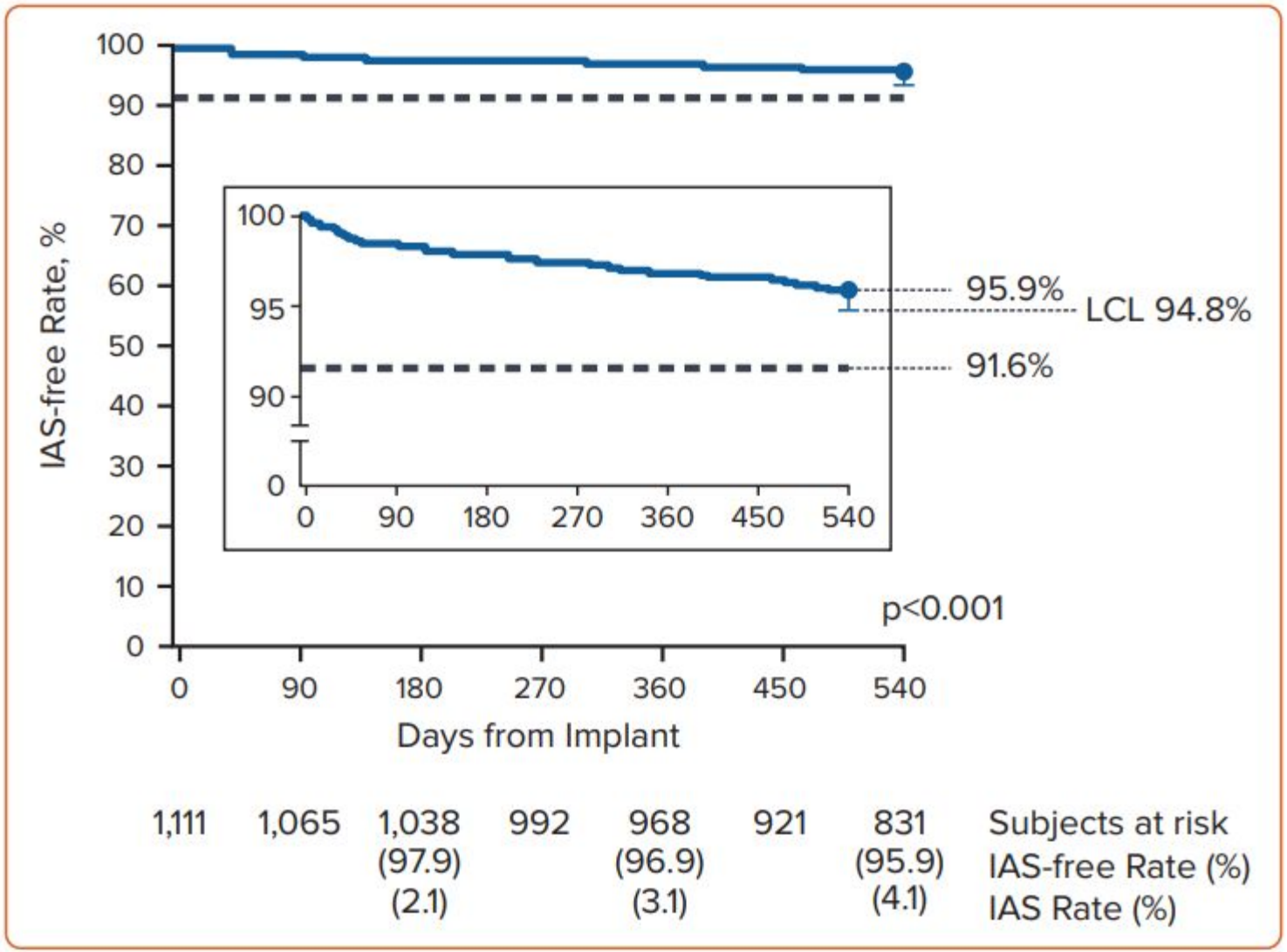
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 3.08$, df = 8 (p=0.93); $I^2 = 0\%$

Test for overall effect: Z = 5.08 (p<0.00001)

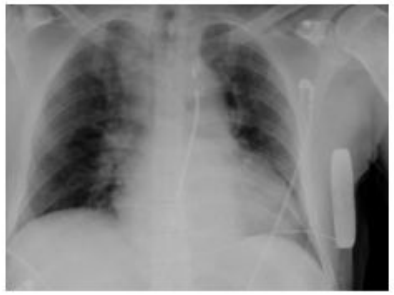


ARRHYTHMIA & ELECTROPHYSIOLOGY REVIEW,2022

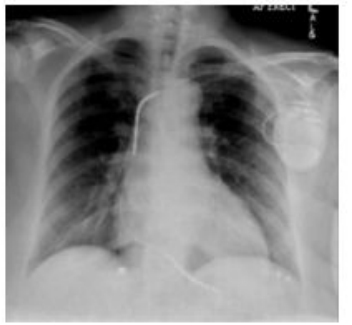
Inappropriate Shock-free Rate in the UNTOUCHED Study



Circulation 2021;143:7–17.
https://doi.org/10.1161/CIRCULATIONAHA.120.048728;
PMID: 33073614.



Factors Influencing Selection of S-ICD vs. TV-ICD



Favors S-ICD

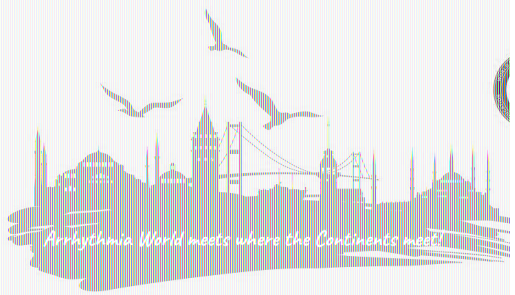
- Limited vascular access
  - Venous occlusion
  - Venous anomaly
- Congenital heart disease
  - No venous access to heart
  - Intra-cardiac shunt
- Prior transvenous ICD infection
- Prior bacteremia
- High risk for infection
  - Immunodeficiency
  - Diabetes
  - Renal dysfunction
  - Immunosuppressive therapy
- On hemodialysis
  - High risk for infection
  - Need for venous access

Favors TV-ICD

- Young age
  - Need for multiple leads in lifetime
  - Active with increased risk lead failure
- Hypertrophic cardiomyopathy
  - High defibrillation energy requirement with TV-ICD
- Channelopathies
  - Index arrhythmia VT/PMVT
  - Often young patients
- Women
  - Higher risk complications TV leads compared with men
  - Cosmetic appearance/concealed
- Patient preference

- Need for bradycardia pacing
- Need for CRT
- Known need for ATP for frequent MMVT, without planned VT ablation
- Failed ECG screen (high risk inappropriate shocks)

JL Tan,A Russo.Heart Rhythm O2 2022;3:589–596



Indications for S-ICD implantation	Recommendation (level of evidence)
Missing or complicated transvenous access (especially in congenital heart disease)	I (B)
History of ICD extraction due to complications (especially after infections or thrombosis)	I (B)
Increased risk for infection (eg, diabetes, dialysis)	I (B)
Mechanical Tricuspid Replacement	I (C)
Severe tricuspid valve regurgitation	IIa (C)
Inherited arrhythmia syndromes or idiopathic VF	IIa (C)
Children and adolescents	IIa (C)
Frequent sportive activities	IIa (C)
Weak patient compliance (eg, after twiddler syndrome)	IIb (C)
Bridge to heart transplantation	IIb (C)
Indication for bradycardia pacing or cardiac resynchronization	III (C)
Expected need for anti-tachycardia pacing (monomorphic VT)	III (C)
Failed pre-implantation screening	III (C)

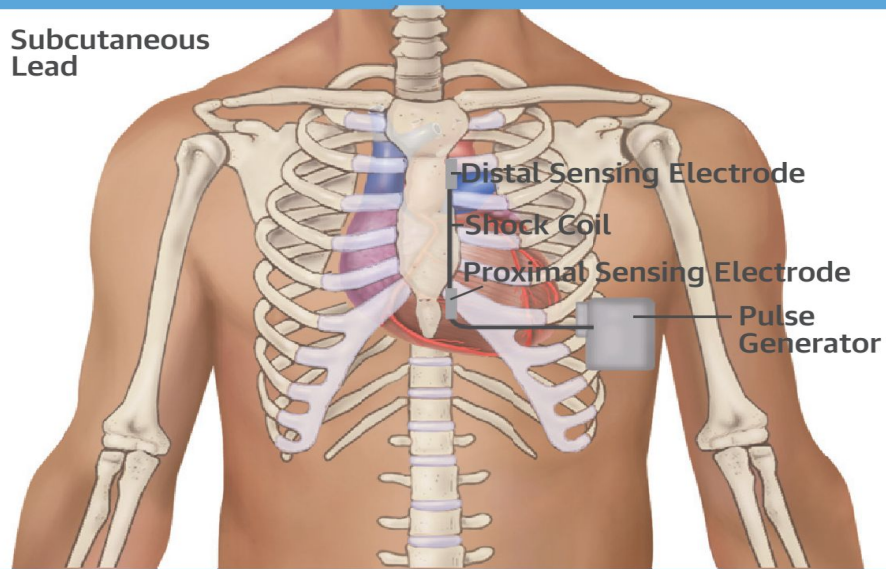
Clin Cardiol DOI: 10.1002/clc.23432 ,2020

Current limitations of the S-ICD

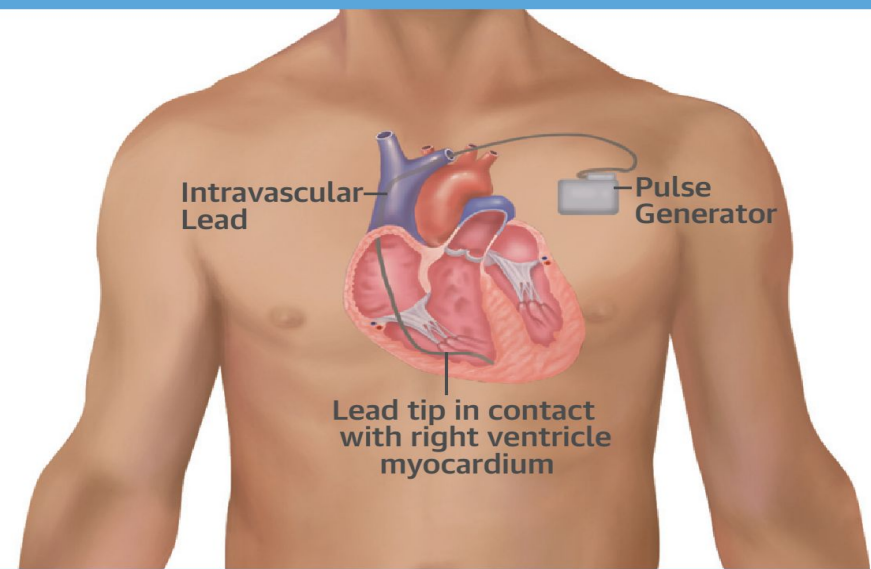
- Shorter battery lifespan,
- Larger PG size,
- Lack of pacing support,
- Lack of direct atrial arrhythmia recording.

(Major improvements and advancements have been made in S-ICD technology over the past few years. These include enhanced battery longevity, smaller PG size, and algorithms to help with detection of atrial arrhythmias despite absence of an atrial lead.)

S-ICD



Transvenous ICD



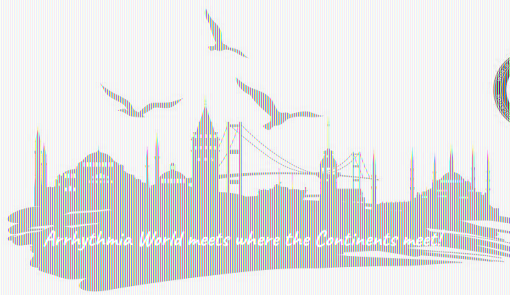
S-ICD Advantages	Transvenous ICD Advantages
• Eliminate need for vascular access	• Pacemaker and ATP functionality
• Possible to implant without fluoroscopy	• Smaller pulse generator
• Reduced mid-term risk of lead malfunction	• Better battery longevity
• Eliminate certain procedural risks (e.g. pneumothorax, tamponade)	• Shorter charge time-faster shock delivery
• Improved arrhythmia discrimination	• Able to deliver CRT
• Relative ease of extraction	• No pre-implant ECG screening required
• Hardware infections not associated with endocarditis	• Long-term follow-up data available

Lewis, G.F. et al. J Am Coll Cardiol. 2016; 67(4):445–54.

SUMMARY

- S-ICD has been shown to have comparable efficacy, reliability, and safety outcomes compared to the transvenous implantable cardioverterdefibrillator (TV-ICD) for the prevention of sudden cardiac death (SCD) in patients who do not have pacing indications.

- When recommending ICD for the primary or secondary prevention of SCD, patients should be given the option of an S-ICD with a high level of recommendation in the absence of pacing indications.



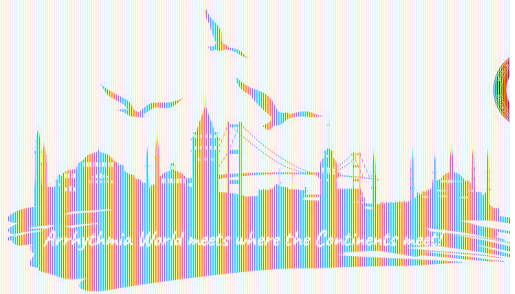
SUMMARY

- The S-ICD may be preferred over the TV-ICD in patients at high risk for cardiac implantable electronic device infection, those with limited vascular access, and patients on dialysis in the absence of pacing indications.
- The S-ICD also may be preferred in younger patients, who may need multiple devices and leads throughout their lifetime, and in women, who are at higher risk for TV-ICD complications, in the absence of pacing indications.
- It is important to emphasize that the S-ICD should be included in the shared decision-making process, when offering ICD therapy for the primary or secondary prevention of SCD in patients who meet implantation criteria without pacing indications.

17th WORLD CONGRESS of ARRHYTHMIAS

2-4 November, 2023 İstanbul/TURKEY

Elite World Convention Center



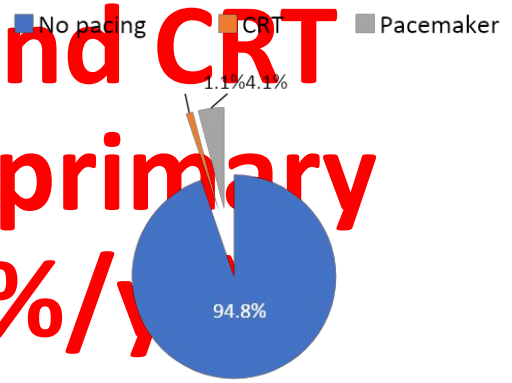
SUMMARY

For the upcoming fourth generation, parallel processing of all three vectors is expected to provide improved sensing properties and increaing the accuracy of discrimination, thus minimizing the number of screening failures and overcome the need of vector reprogramming. As pulse generator size is still an issue in children, adolescents, or patients with low body mass index, the development of smaller device cans is expected in future. As mentioned above, an intermuscular device implantation already enabled efficient shocks using lower energies in the DFT testing.37 Finally, one future concept is to pair a leadless pacemaker in VVI mode with the S-ICD from the second generation, in order to provide ATP and (post-shock) bradycardia pacing for patients who are expected to benefit or have a respective indication. Currently, the lack of ATP is still a major issue for a better acceptance of the S-ICD among cardiologists. However, ATP should be programmed more conservatively, since the randomized MADIT-RIT trial revealed a higher mortality associated with appropriate ATP therapies in the “conventional” (empiric) ICD programming arm.57 One explanation for this finding might be a significantly higher mortality in patients with accelerated VT following appropriate

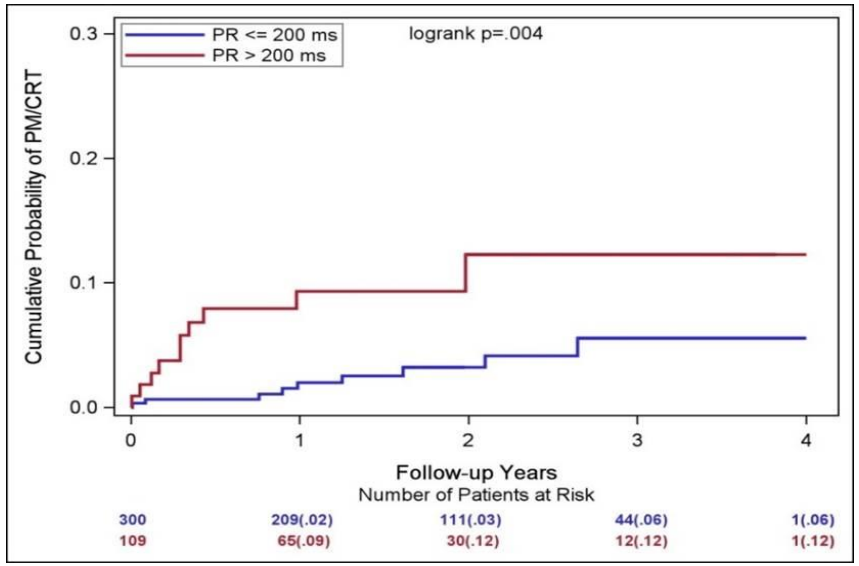
Need for Brady Pacing and CRT develops in minority of primary prevention patients (~2%/y)

MADIT-II

- ICD indicated patients in the control arm of MADIT-II (N=458) median follow-up of 20 months



- Baseline PR interval >200 ms significantly predicted subsequent PM/CRT implantation (HR=3.07, 95% CI: 1.24-7.57, p=0.02)



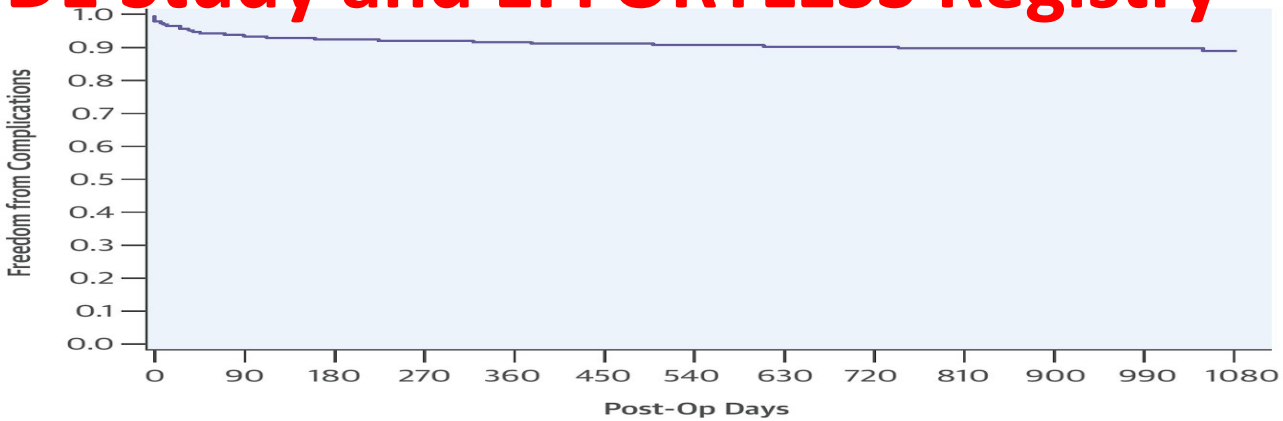
Kutyifa. et al. The Need for Pacing in patients who qualify for an ICD: Clinical Implications. *ESC* 2014; Abstract P4346

Long-Term safety and efficacy of the S ICD:Pooled analysis of IDE Study and EFFORTLESS Registry

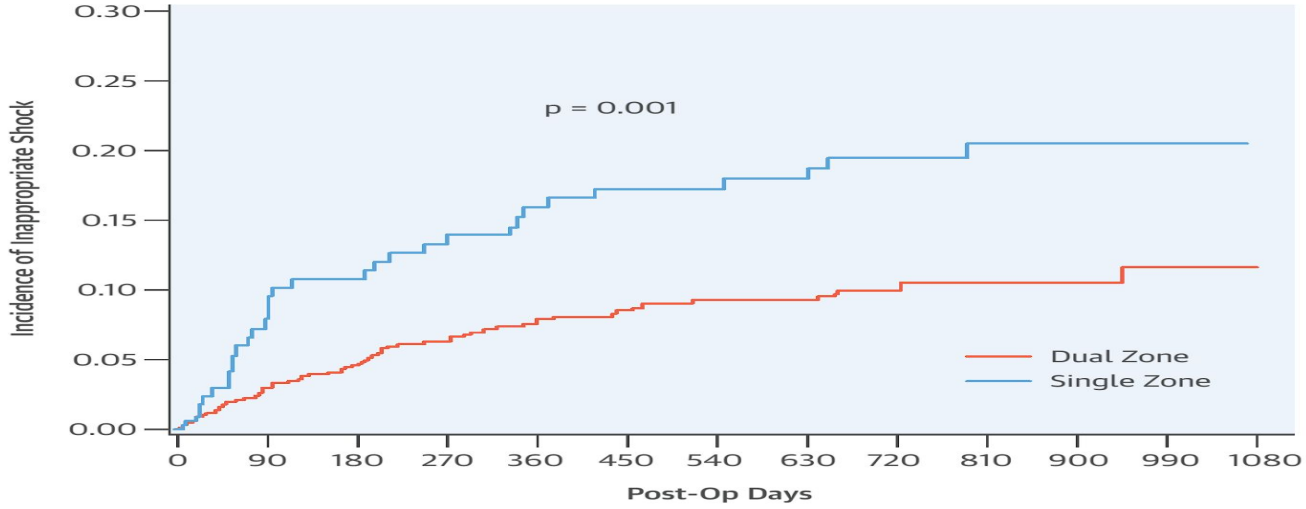
- 882 patients
- 3 yrs FU
- 90.1 % events terminated with 1 shock
- 98.2 % were terminated within the 5 available shocks
- 3-yr inapp shock 13.1 %
- 3-yr all cause mortaity 4.7 %
- Device related complications in 11.1 % patients at 3-yrs
- 3 devices (0.3 %) were replaced for ventricular pacing
- No electrode failures/No s-ICD related endocarditis or bacteriemia
- 6-month complication rate decreased by quartile of enrollment

J Am Coll Cardiol 2016;67:445-54

Long-Term safety and efficacy of the S ICD:Pooled analysis of IDE Study and EFFORTLESS Registry



No. at Risk	878	791	731	707	650	591	525	414	303	217	162	123	105
K-M Estimate (%)	99.0	93.4	92.3	92.0	91.4	90.9	90.6	90.2	90.0	89.7	89.7	89.7	88.9



Dual Zone	No. at Risk	688	634	576	546	494	441	378	279	180	120	89	66	56
	K-M Estimate (%)	0.0	3.0	4.6	6.2	7.7	8.5	9.3	9.3	10.0	10.5	10.5	11.7	11.7
Single Zone	No. at Risk	170	153	141	134	126	122	117	108	96	75	53	43	36
	K-M Estimate (%)	0.0	7.8	10.8	13.3	15.9	17.3	17.3	18.0	19.5	20.5	20.5	20.5	20.5

Burke, M.C. et al. J Am Coll Cardiol. 2015; 65(16):1605–15.

Ideal Device Placement