Transvenous or Non-transvenous ICD in ACHD

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COI Disclosure

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to disclose concerning the presentation

Disclosure

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- Other:

Introduction

- Sudden cardiac death is a major cause of mortality in ACHD patients
  - 19% to 26% of mortality
- The indications for ICD implantation in ACHD patients are still not well established
- It is unclear whether non-transvenous ICD systems in patients with CHD differ from standard transvenous systems
  - with respect to safety and efficacy

Risk estimates for arrhythmic events and bradycardias in ACHD

	Supraventricular arrhythmias			Ventricular arrythmias and SCD		Bradycardia			
						SND		AV block	
Type of CHD	AVRT	IART/ EAT	AF	Sustained VT	SCD	Congenital	Acquired	Congenital	Acquired
Secundum ASD		++	++			(+)	+		(+)
Superior sinus venosus defect		++	+				+		
AVSD/primum ASD		++	++	(+)		(+)		(+)	++
VSD		+	(+)	+	(+)[a]				+
Ebstein anomaly	+++	++	+	(+)	++[b]		++		
TOF		++	++	++	++		+		+
TGA									
Atrial switch		+++	+	++[c]	+++[b]		+++		+
Arterial switch		+		+[c]	(+)		(+)		
ccTGA	++	+	+	(+)	++[b]			+	++
Fontan operation									
Atriopulmonary connection		+++	++		+[b]		++		
Intracardiac lateral tunnel		++	+		+[b]		++		
Extracardiac conduit		+	+		+[b]		+		
Eisenmenger physiology Incompletely palliated CHD		++	++		++[d]				

©ESC

Complex CHD;
limitations in TV-ICD implantation due to anatomical variations and previous surgeries

2020 ESC guideline

KHRS 2023

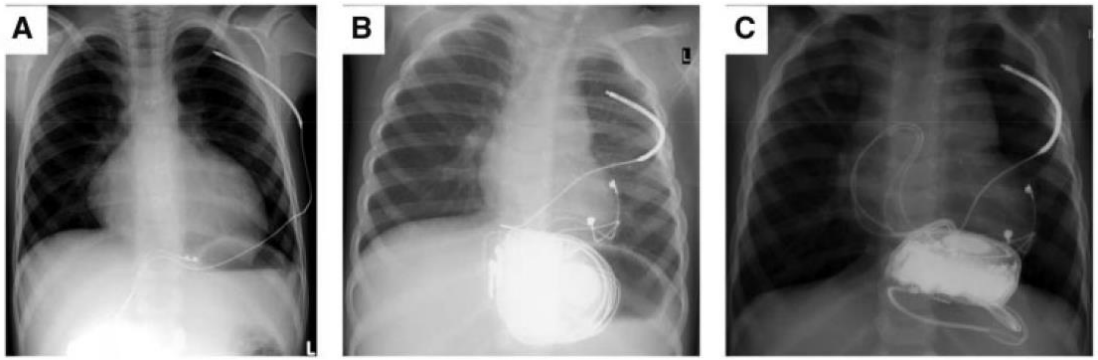
Lead Implant Route for Patients With CHD in Implantable Cardioverter Defibrillator Registry

more complex forms of CHD underwent nontransvenous lead implantation

Characteristics	Total, N (%)	Transvenous Leads, N (%)	Nontransvenous Leads, N (%)	*P* Value
Total	3139 (100)	3039 (100)	100 (100)	…
Male	1129 (36)	1088 (36.0)	41 (41.0)	…
Initial implant	1683 (53.6)	1628 (53.6)	55 (55.0)	…
Age, y	53.0 (18.2)	53.2 (18.1)	45.7 (19.1)	0.04
Height, cm	170.5 (12.1)	170.7 (35.8)	166.2 (19.3)	<0.01
Weight, kg	82.6 (22.7)	82.6 (22.6)	80.4 (24.6)	…
CHD type				
Atrial septal defect	1304 (41.5)	1262 (41.5)	42 (42.0)	…
Ventricular septal defect	951 (30.3)	917 (30.2)	34 (34.0)	…
Tetralogy of Fallot	751 (23.9)	740 (24.3)	11 (11.0)	0.02
Transposition of great vessels	376 (12.0)	354 (11.6)	22 (22.0)	<0.01
Ebstein anomaly	81 (2.6)	76 (2.5)	5 (5.0)	…
Hypertrophic cardiomyopathy*	75 (2.4)	75 (2.4)	0 (0.0)	…
Common ventricle	25 (0.8)	20 (0.7)	5 (5.0)	<0.01
Structural abnormality type–other†	218 (6.9)	208 (6.8)	10 (10.0)	…

Circ Arrhythm Electrophysiol. 2014;7:1092-1100

T-ICD vs. extracardiac ICD



195 children and patients with congenital heart disease

Congenital heart disease	*n*=94 (48%)
Cardiomyopathy	*n*=61 (31%)
Channelopathy	*n*=40 (21%)

Transvenous ICD *n*=153 (78%)

Appropriate shocks *n*=20 (13%)*

Inappropriate shocks *n*=17 (11%)

P=0.02

EC-ICD *n*=42 (22%)

Appropriate shocks *n*=12 (29%)*

Inappropriate shocks *n*=5 (12%)

Inappropriate shocks–reasons

SVT/AT	*n*=17 (76%)
Lead failure	*n*=3 (14%)
T-wave oversensing	*n*=1 (5%)
External AC current	*n*=1 (5%)

Lead failure during follow-up

Transvenous ICD

n=11/153 (7%)*

P=0.001

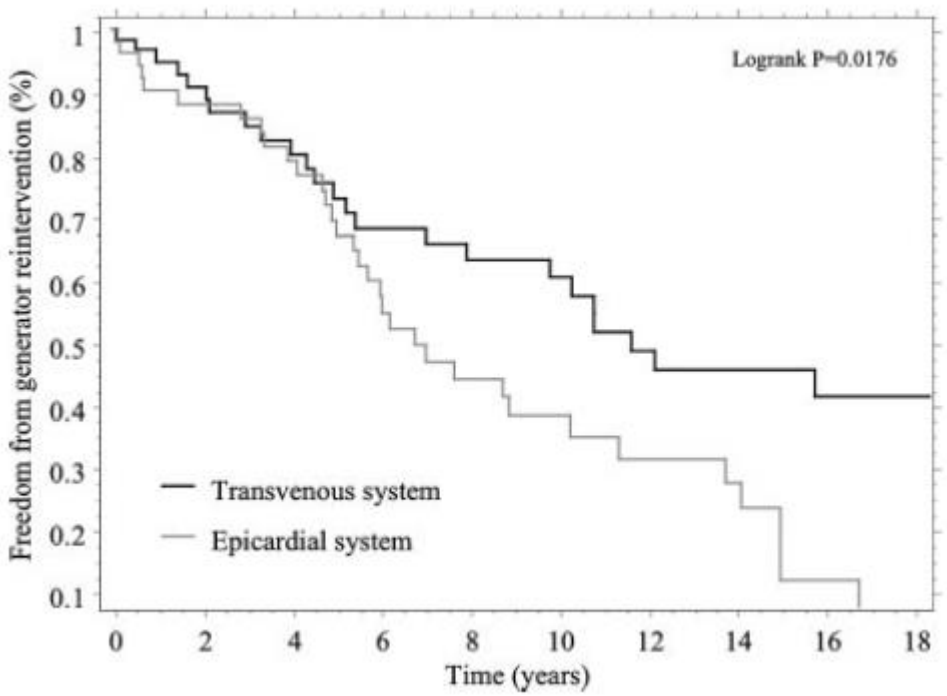
EC-ICD

n=12/42 (29%)*

Europace (2019) 21, 106–113

Transvenous vs Epicardial lead

- Epicardial leads were associated with higher atrial and ventricular thresholds and shorter generator longevity (HR, 1.9)

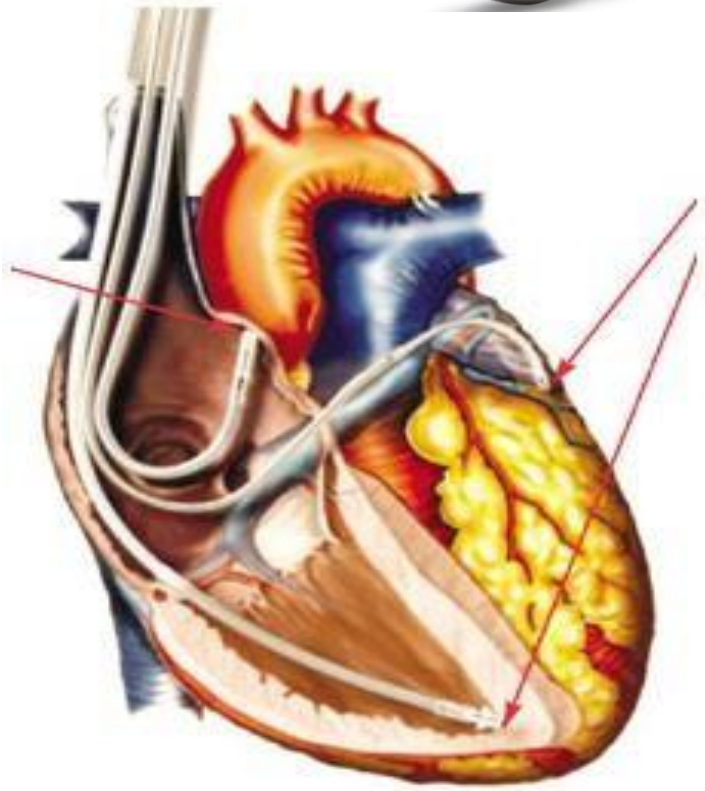


	Transvenous System (n=64)	Epicardial System (n=56)
Acute complication, n (%)		
Hematoma	4 (6.3)	1 (1.8) retroperitoneal
Pneumothorax	0 (0)	1 (1.8)
Lead displacement	6 (9.4)	2 (3.6)
Oversensing	0 (0)	1 (1.8)
Hemorrhage requiring transfusion	0 (0)	4 (7.1)
Pacemaker syndrome	1 (1.6)	0 (0)
Death	0 (0)	1 (1.8)
Late complication, n (%)		
Lead related		
Intravascular constriction	2 (3.1)	0 (0)
Lead dislodgement/failure to capture	11 (17.2)	12 (21.4)
Oversensing	0 (0)	1 (1.8)
Endocarditis	1 (1.6)	3 (5.4)
Generator related		
Pain	0 (0)	3 (5.4)
Erosion	1 (1.6)	0 (0)
Infection	2 (3.1)	2 (3.6)
Migration	0 (0)	1 (1.8)

Circulation. 2006;113:2391-2397

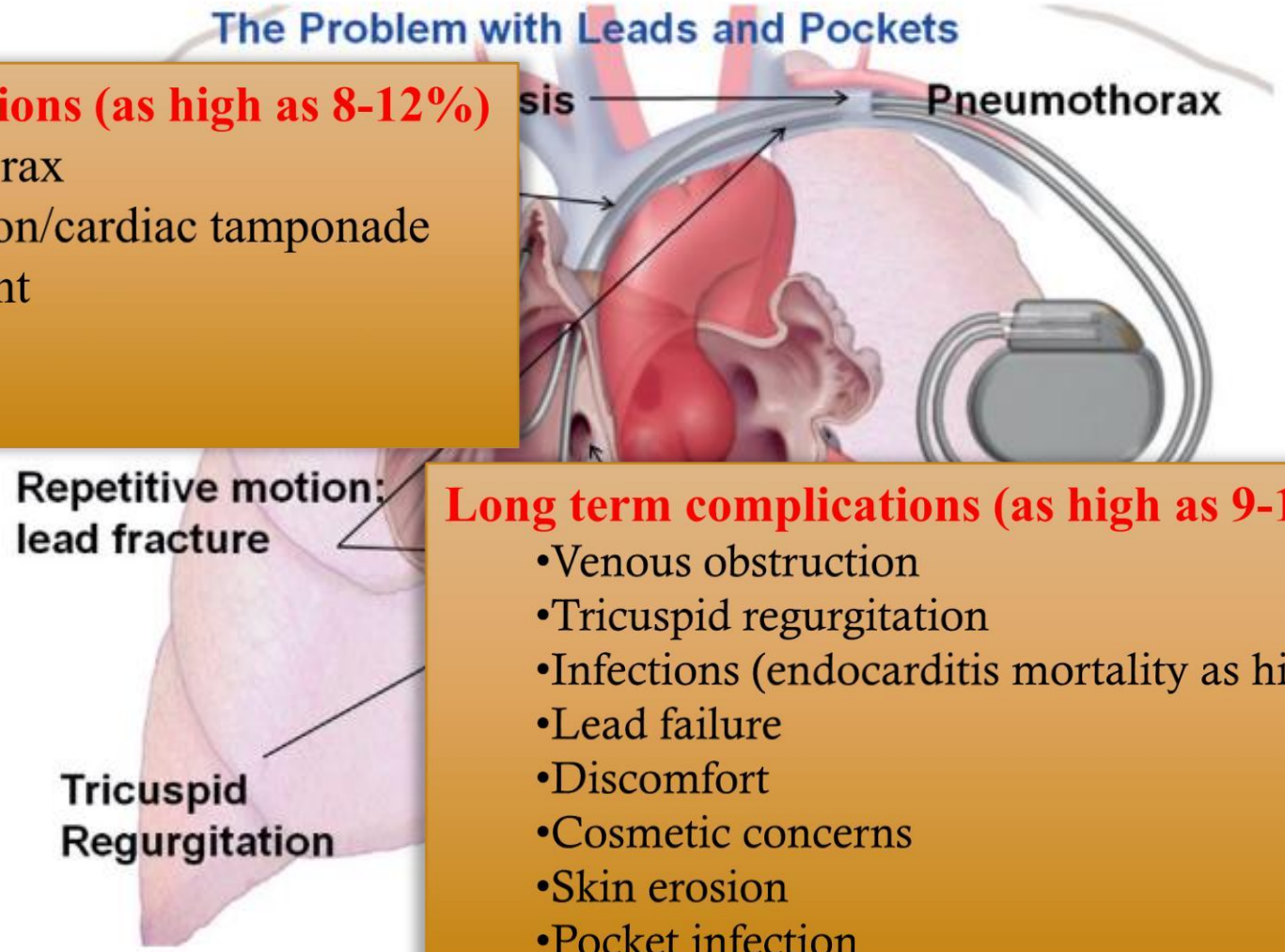
Transvenous ICD system

- The current ICD approach is effective
  - 11% ICD patients suffer complications during or shortly after implant



Reynolds et al JACC Aug 2006

Limitations of CIED



Short term complications (as high as 8-12%)

- Pneumo/hemothorax
- Pericardial effusion/cardiac tamponade
- Lead dislodgement
- Hematoma
- Infection

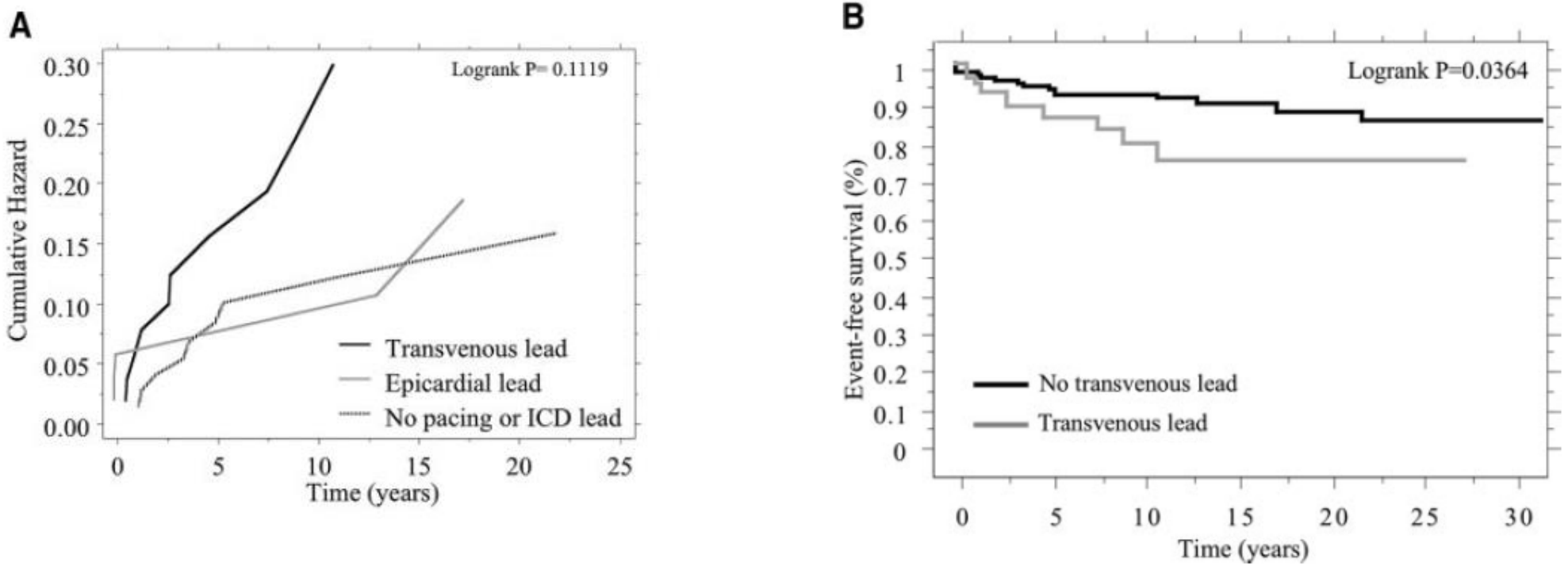
Long term complications (as high as 9-10%)

- Venous obstruction
- Tricuspid regurgitation
- Infections (endocarditis mortality as high as 12-31%)
- Lead failure
- Discomfort
- Cosmetic concerns
- Skin erosion
- Pocket infection

Madhavan, M. et al. J Am Coll Cardiol. 2017;69(2):211-35

Transvenous vs, Epicardial lead

Transvenous leads incur a >2-fold increased risk of systemic thromboemboli in patients with intracardiac shunts



-Risk factors were older age (HR, 1.05), atrial fibrillation or flutter (HR, 6.7), and ongoing phlebotomy (HR, 14.4)

-Aspirin or warfarin prescribed was not protective

Circulation. 2006;113:2391-2397

ICD leads in congenital heart disease patients

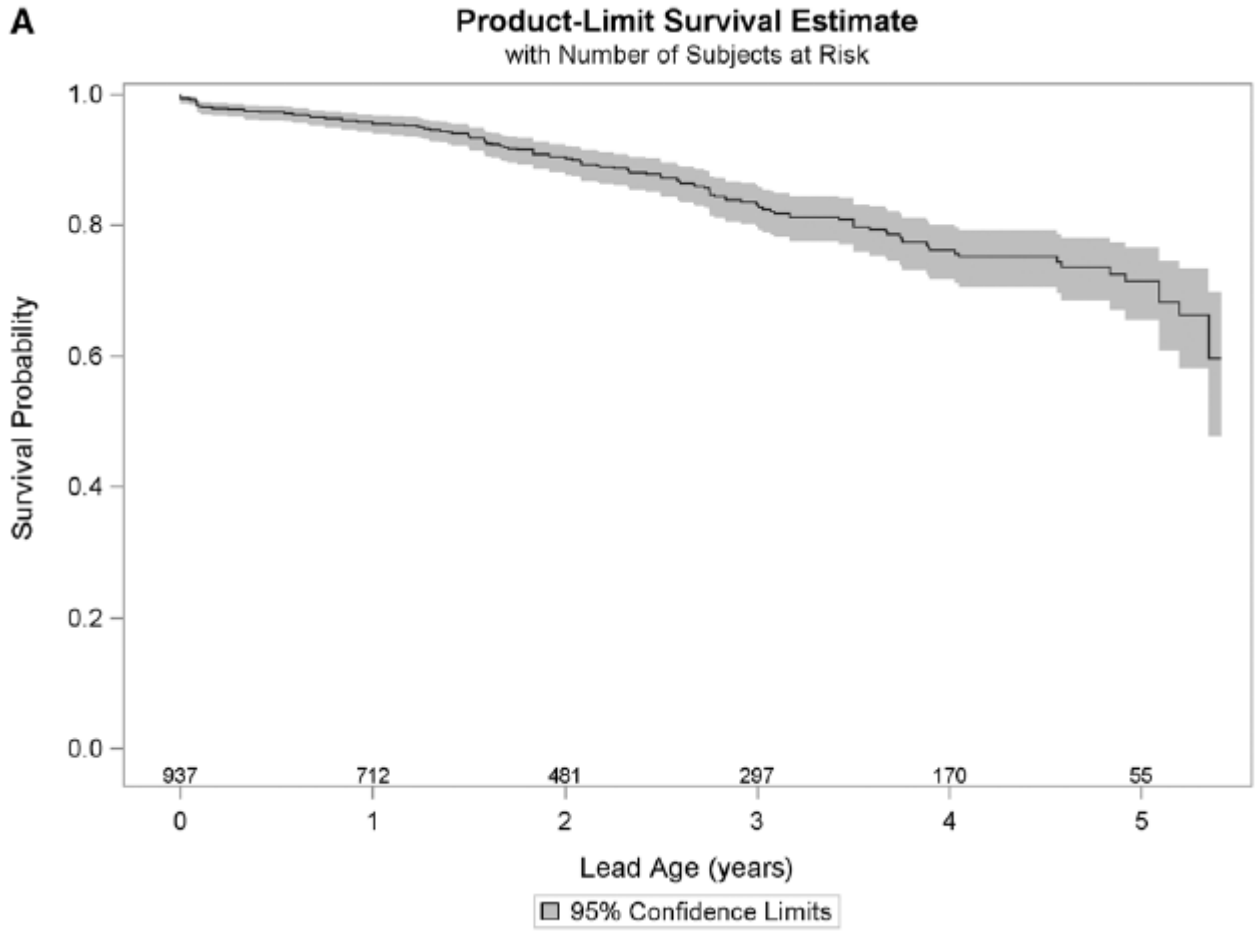
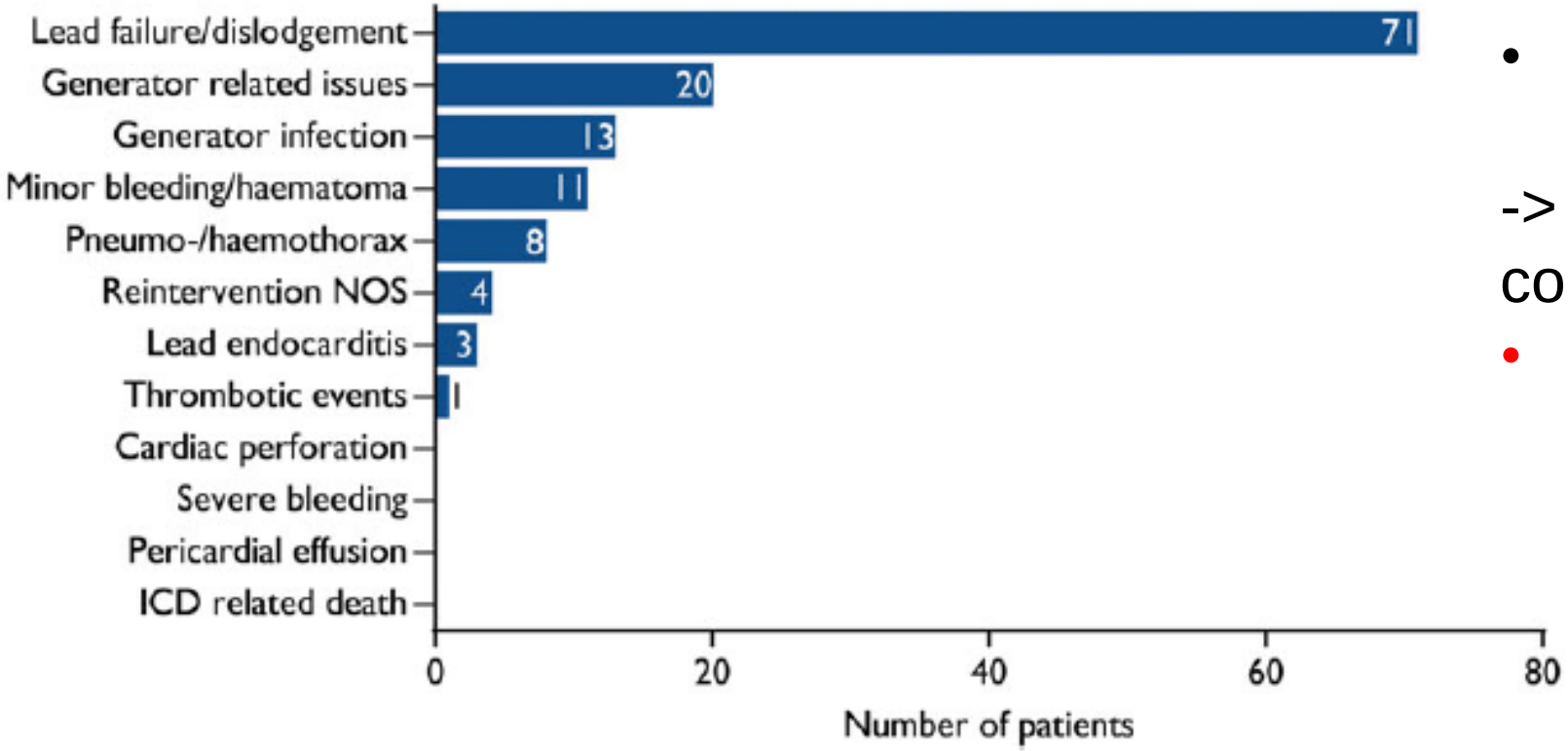


Table 3. Results of a Cox Proportional Hazard Model for Predictors of the First Defibrillator Lead Failure for All Patients, Stratified by Era (2005–2007 and 2008–2010)

Variable	HR (95% CI)	*P* Value
Patient characteristics		
Patient age at initial implant (per 1 y)	0.97 (0.94–0.99)	0.013
Age at implantation ≥12 y	0.55 (0.35–0.87)	0.011
Structural heart disease	1.23 (0.81–1.86)	0.330
Single-chamber ICD system	0.70 (0.45–1.08)	0.103
Lead characteristics		
Fidelis leads	4.52 (2.45–8.34)	<0.001
Single coil	1.35 (0.91–2.01)	0.132

Circulation. 2013; 127:2393-2402.

Numerous ACHD patients experienced inappropriate shocks and ICD-related complications
(26% complications vs. 14% in 3.8 years for at SCD-HeFT)



- ACHD patients are younger and more active

-> lead failure/dislodgement is common

- Generator changes also need to be done more

To overcome Limitations of Transvenous Leads

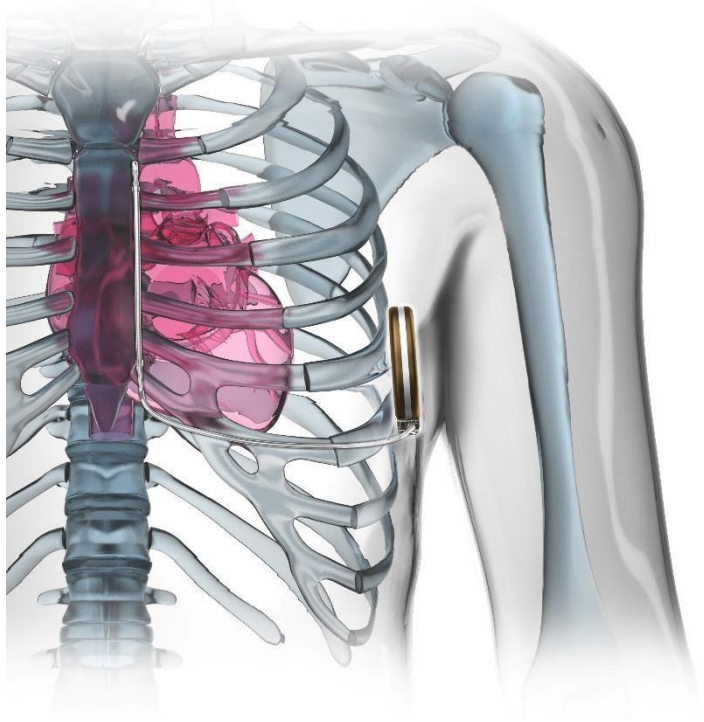
- **Anatomical Limitations**
  - Venous access issues

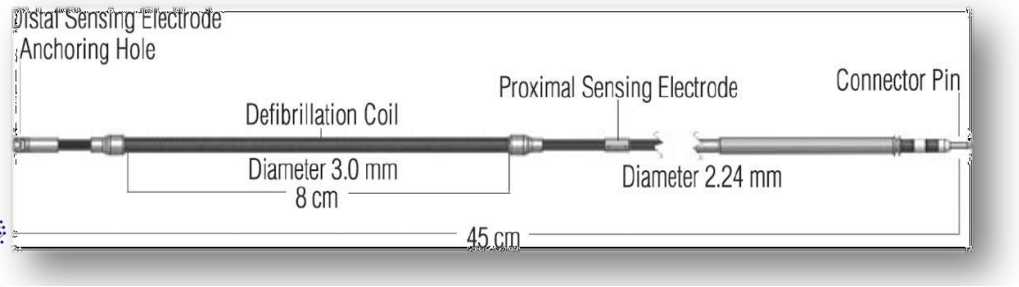
- **Implant risks**
  - Pericardial effusion/cardiac tamponade, perforation, pneumothorax , lead dislodgement, endocarditis, systemic infection, death

- **Lead failure risks**
  - Inappropriate shock / loss of therapy

- **Explant risks**
  -Vessel dissection, perforation or occlusion, valve damage, bleeding, tamponade, systemic infection

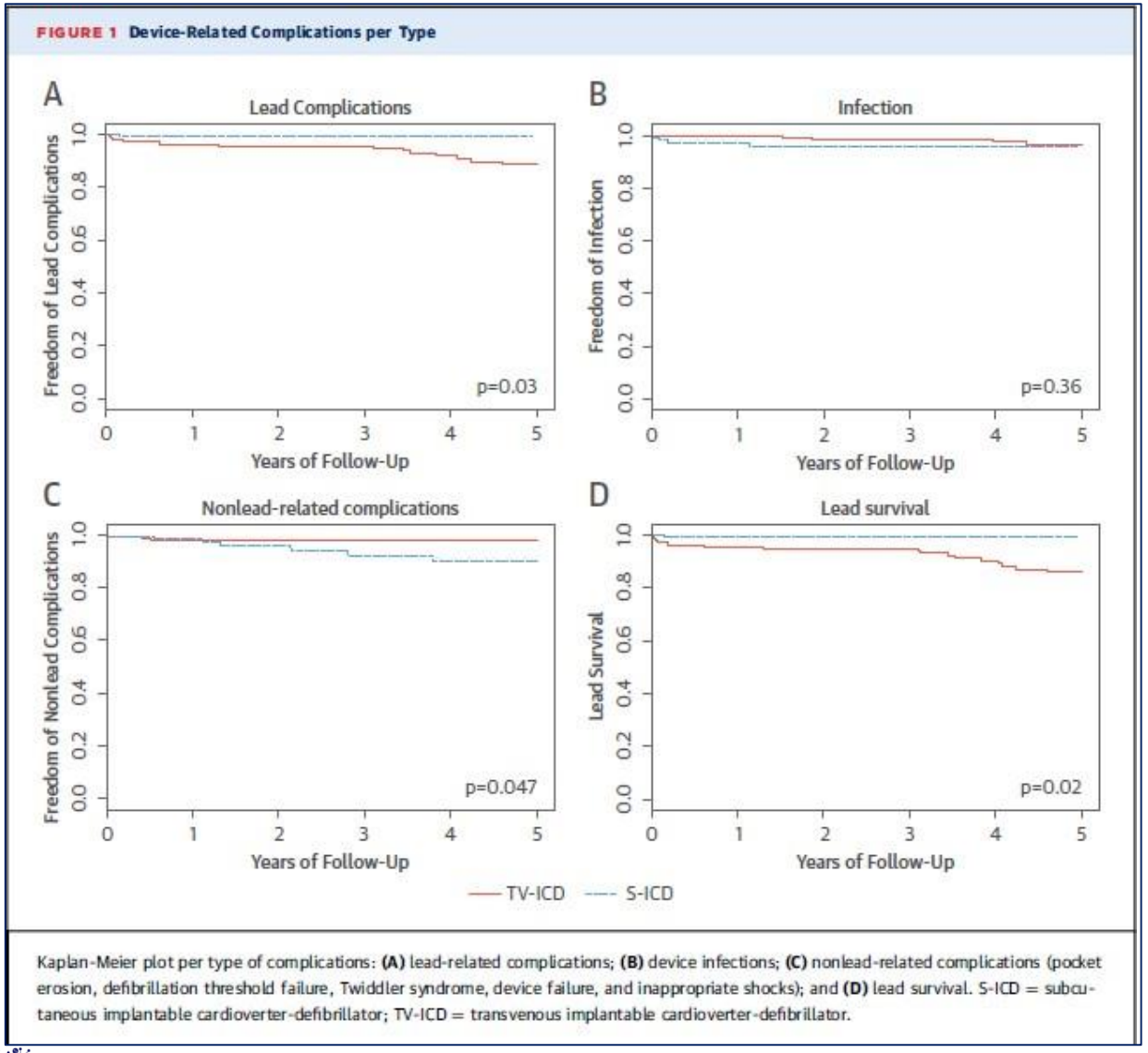
Subcutaneous ICD





- **Entirely subcutaneous**
- **Does not require leads in the heart, leaving the vasculature untouched**
- **Placed using anatomical landmarks, reducing the need for fluoroscopy at implant**
- **provide effective detection and treat ment of VT/VF**

TV-ICD vs S-ICD complications for non-CHD patients



14 times the number of TV ICD lead complications requiring surgical intervention

(11.5% vs 0.8% p=0.03)

Lead survival at 5 years was significantly better for S-ICD vs TV-ICD

(99% vs 86% p=0.02)*

Brouwer, T.F., et al. J Am Coll Cardiol, 2016. 68(19): p. 2047-2055.

Limitation of S-ICD

Volume : 26.5cc
Weight : 60g

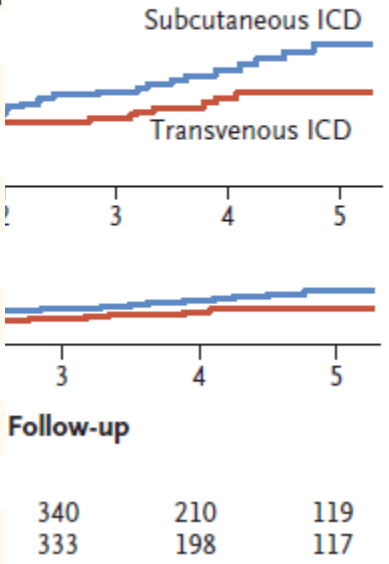
Volume : 59.5cc
Weight : 130g

- Associated with shocks for ventricular tachycardia
- High current is required
- Antitachycardia pacing is not available
- Bradycardia pacing is limited

Devi

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)	

43 (95% CI, 0.89–2.30)



or medication

- Cardiac/noncardiac oversensing: less modifiable

N Engl J Med 2020;383:526-36

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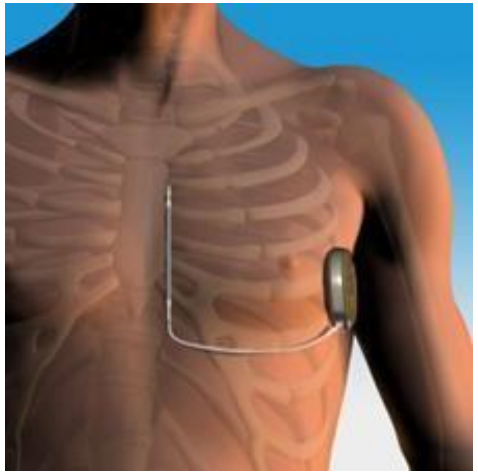
Transvenous (TV) ICDs

- Provides effective defibrillation
- for ventricular tachyarrhythmias
- Provides brady pacing
- Provides ATP for patients with inc essant monomorphic VT
- Provides atrial diagnostics
- Familiar implant technique

The S-ICD System



- Provides effective defibrillation
- for ventricular tachyarrhythmias
- No risk of vascular injury
- Low risk of systemic infection
- Preserves venous access
- Avoids risks associated with endova scular lead extraction
- Fluoroscopy not required

Most candidates for S-ICD in ACHD

- single ventricle
- limited transvenous options for ICD implantation
- intracardiac shunts

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 (S11.1-1–S11.1-5).
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 (S11.1-1–S11.1-4).
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 (S11.1-1–S11.1-4,S11.1-6–S11.1-8).

J Am Coll Cardiol. 2018 Oct 2;72(14):1760

Unique considerations for ACHD patients

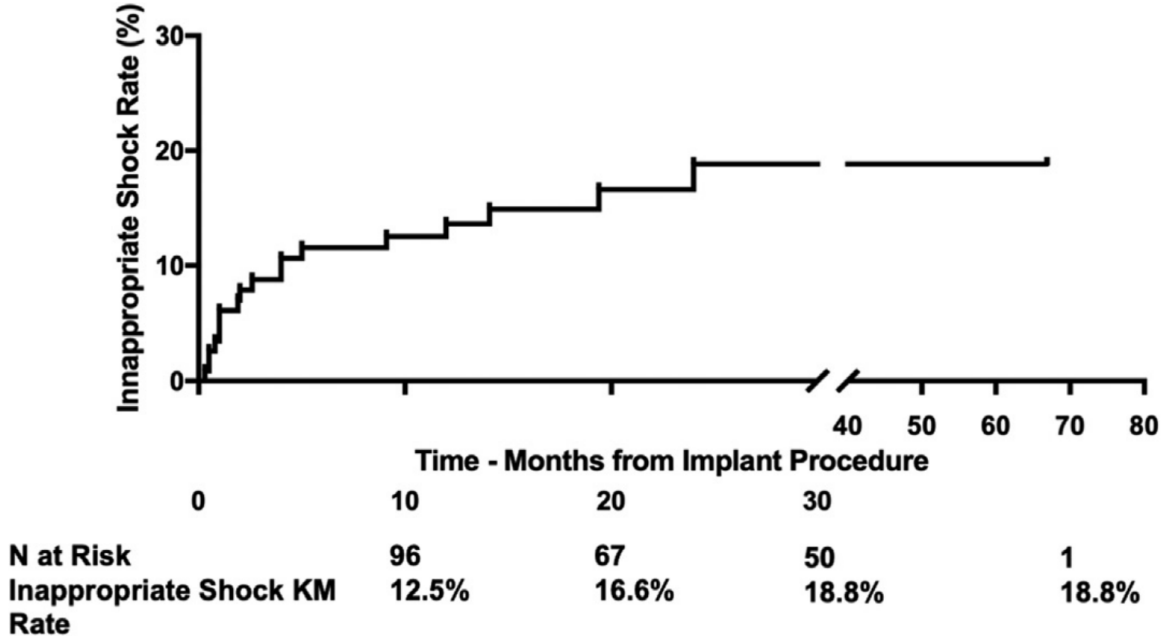
- various anatomic constraints
- lack of vascular access
- the high rate of lead malfunction
- possibility of a further lead-associated tricuspid regurgitation

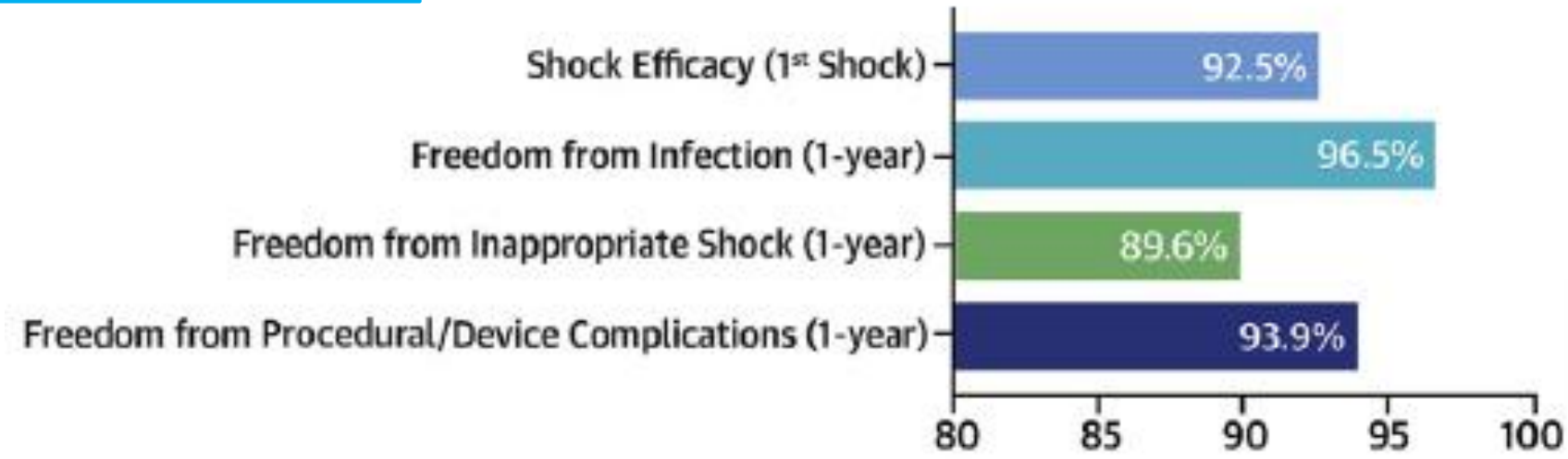
-> can even facilitate ventricular arrhythmias occurrence

S-ICD Implantation in Pediatric Patients and Those With Congenital Heart Disease

- Effective acute conversion and appropriate therapy delivery
- Inappropriate shock rates are comparable to other published literature for transvenous ICDs

in CHD populations

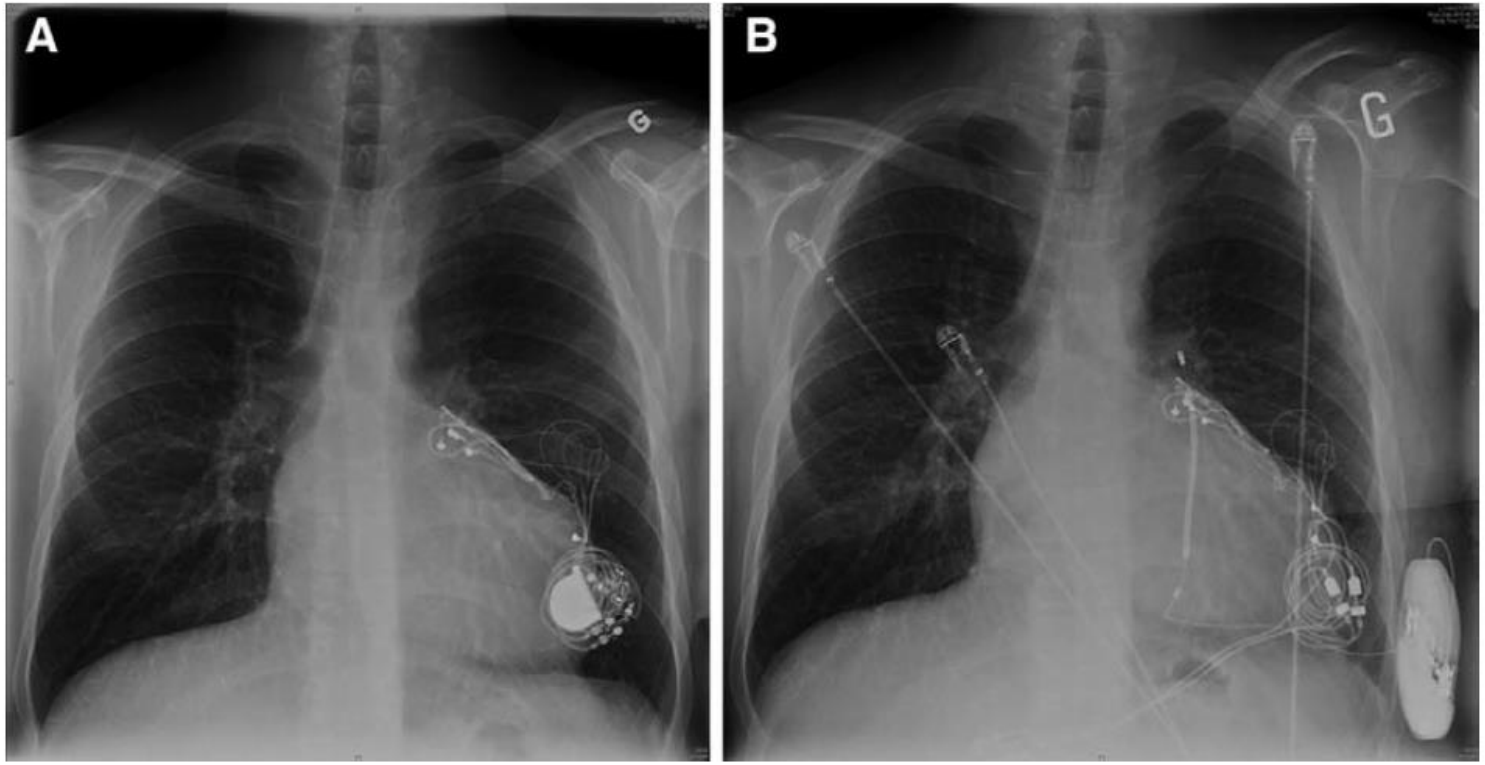




von Alvensleben, J.C. et al. J Am Coll Cardiol EP. 2020

Special considerations for S-ICD placement in the ACHD population

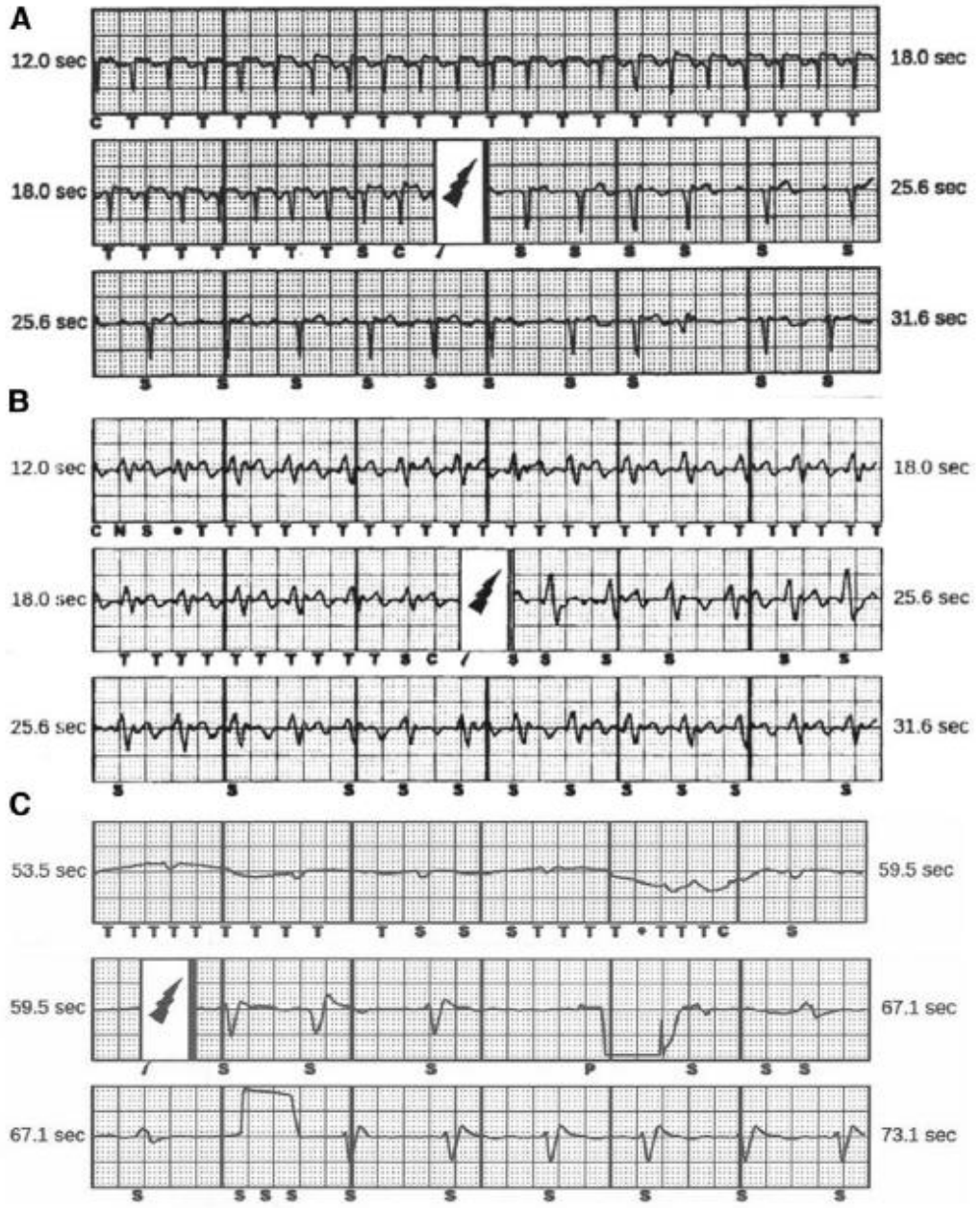
- Abnormalities in ventricular repolarization
- Higher than usual prevalence of supraventricular tachycardia
- An increased potential for interdevice interactions
    - -especially, unipolar pacing



Circ Arrhythm Electrophysiol. 2016;9:e004338.

S-ICD for ACHD

13% of patients received IAS
- due to SVT 40%, T-wave oversensing 40%, and non-cardiac oversensing 20%
- Reprogramming, proper drug therapy, and surgical revision avoided further IAS.



Europace (2023) 25, 460–468
Circ Arrhythm Electrophysiol. 2016;9:e004338.

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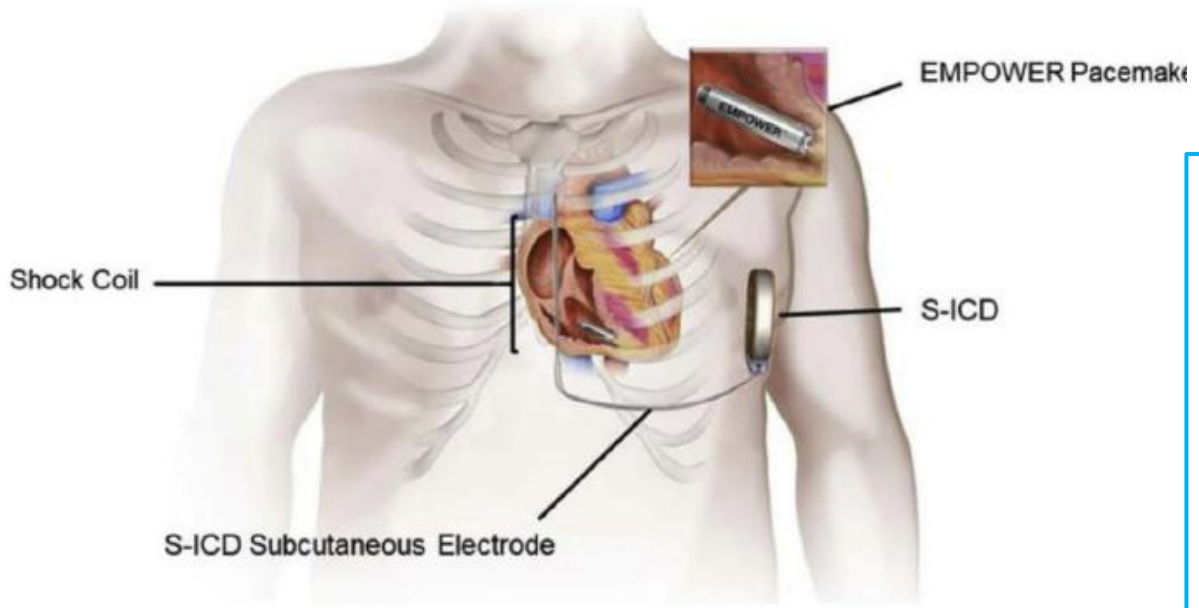
In the future,

- Advances in sensing algorithms and leadless pacing systems
  - could allow for reduced inappropriate shocks and a wider application to varied patient populations
- Demonstrating the efficacy of lower defibrillation outputs
  - would allow for the creation of smaller generator sizes and applicability of the S-ICD

Modular CRM System Program

A



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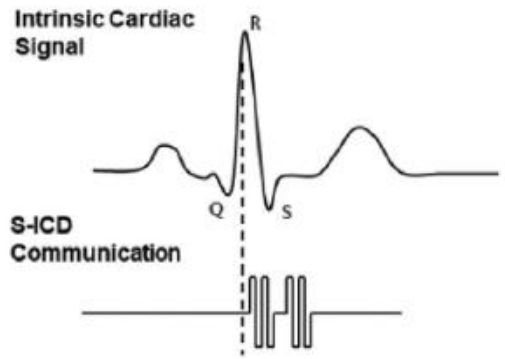
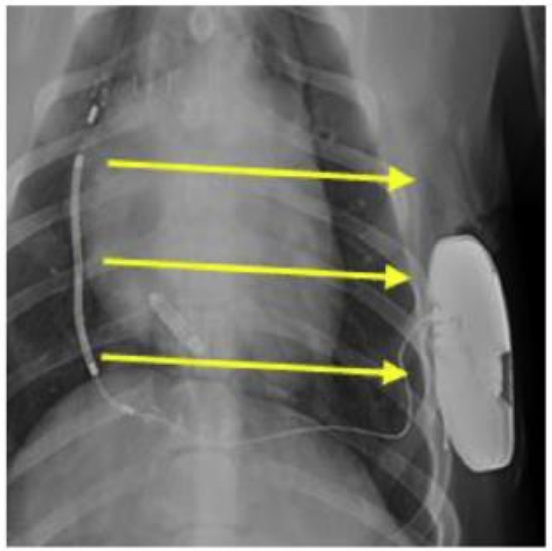


- Communication coupled to sensed R-wave
- Emitted signals are approximately 0.5-4V amplitude and 25kHz frequency
- Built-in redundancy of 2 messages sent

C



- Excellent long-term performance (18mo) in a preclinical model
  -appropriate VVI functionality
  -successful wireless device–device communication
  -ATP delivery
- Human clinical studies are required

Heart Rhythm 2022;19:837–846

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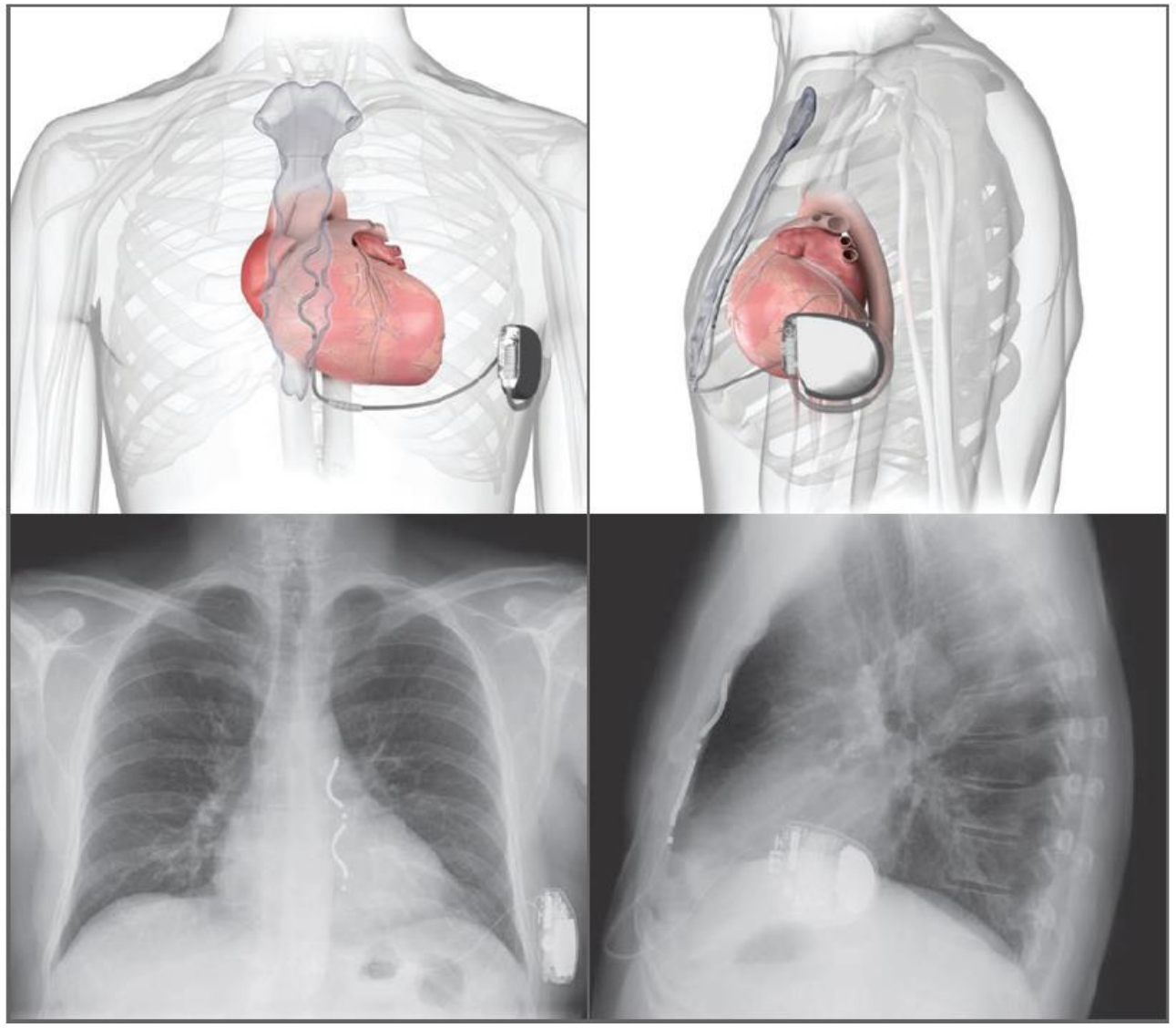
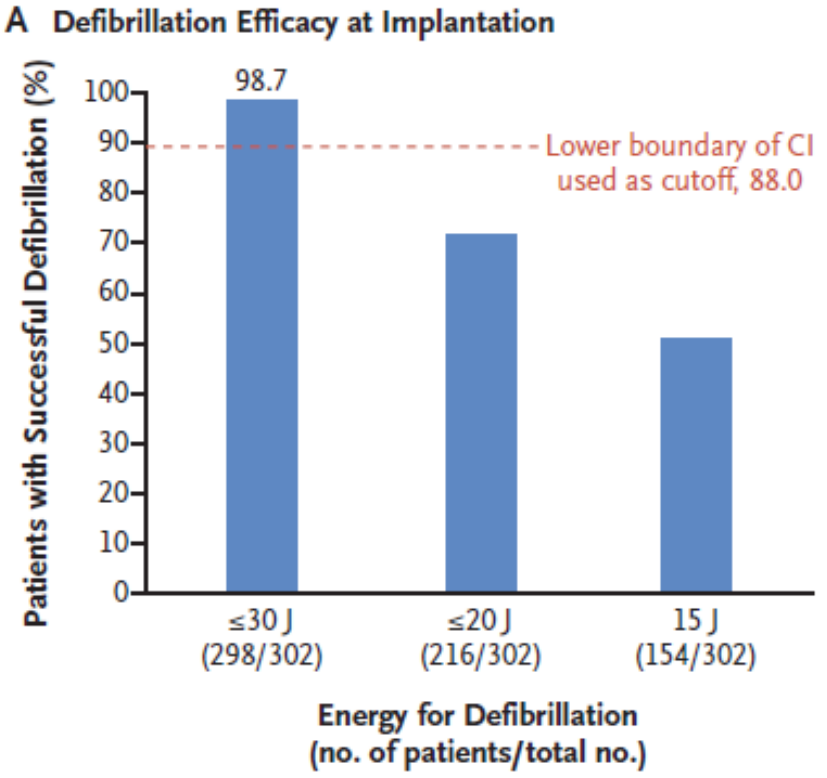
Extravascular ICD



- Enable pause-prevention pacing, antitachycardia pacing
- defibrillation energy similar to that of transvenous ICDs



N Engl J Med 2022;387:1292-302.

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- Biventricular physiology and a systemic LV

  -> follows standard criteria

- For single or systemic RVs is less well established

  -> Indivualized approach

  -> S-ICD implantation is the only available option in some case

  * Epicardial options should be considered if vector testing fails

Europace (2023) 25, 199–210

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Conclusion

- ICD implantation in ACHD patients should be based on a multifactorial decision-making process
  - that takes into account parameters derived from previous studies

- Consider factors such as the patient's age, anatomic constraints, and the need for pacing, etc.

- The significant rates of complications and inappropriate shocks emphasize the importance of carefully weighing the costs and benefits for each individual patient
  - unique characteristics and needs of ACHD patients is crucial

Thank you for your attentions