Latest Update of SICD

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Outlines

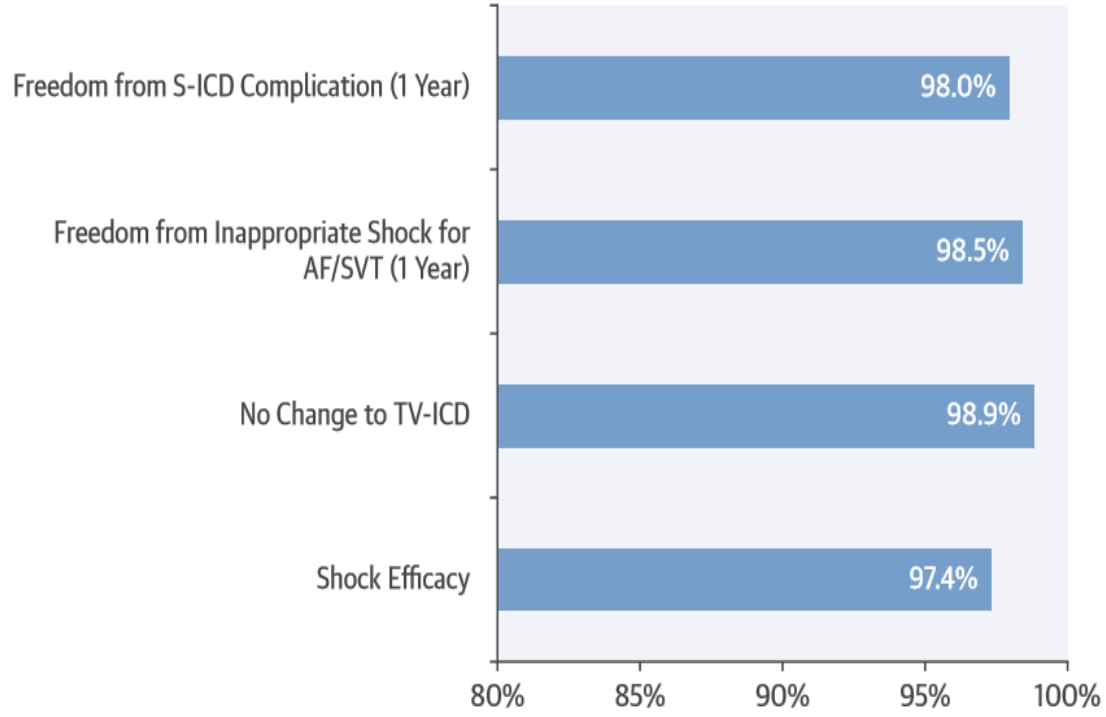
1. Safety and Efficacy of S-ICD
2. Implantation of S-ICD
   - Lead and Device Implant
   - Anesthetic method
   - Device Replacement
3. Future Perspective of S-ICD

Outlines

1. **Safety and Efficacy of S-ICD**
2. Implantation of S-ICD
   - Lead and Device Implant
   - Anesthetic method
   - Device Replacement
3. Future Perspective of S-ICD

EFFORTLESS S-ICD Registry

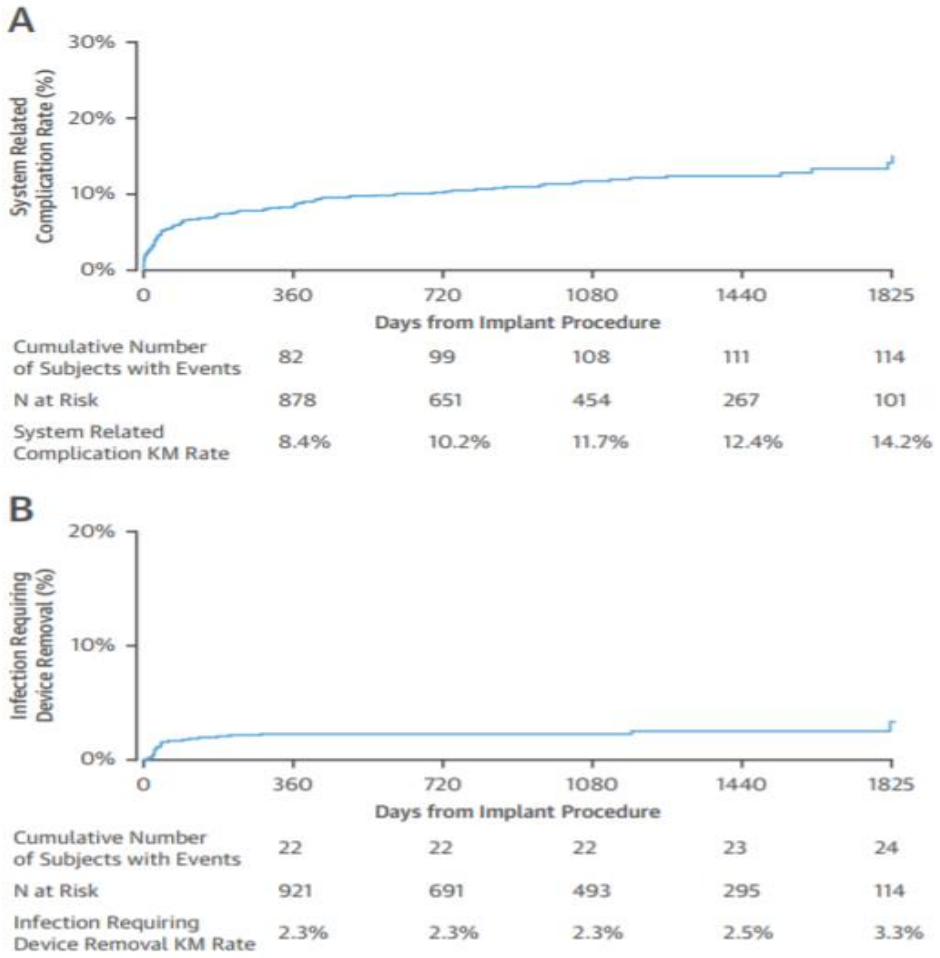
	Overall (N = 985)	Retrospective (n = 489)	Prospective (n = 496)	p Value
Age at implantation, yrs	48 ± 17	45 ± 17	51 ± 16	<0.001
Male	709 (72.0)	338 (69.1)	371 (74.8)	0.05
BMI, kg/m^2	27 ± 6	27 ± 5	28 ± 6	0.06
Ejection fraction, %	43 ± 18	46 ± 18	41 ± 19	<0.001
QRS duration, ms	106 ± 25	104 ± 22	107 ± 27	0.07
Primary prevention	638 (64.9)	307 (62.9)	331 (66.9)	0.19
Ejection fraction ≤35%	301 (57.7)	123 (50.4)	178 (64.0)	0.002
Ischemic	221 (34.6)	87 (28.3)	134 (40.5)	0.001
Secondary prevention	345 (35.1)	181 (37.1)	164 (33.1)	0.19
Ischemic	90 (26.1)	41 (22.7)	49 (29.9)	0.13
Comorbidities				
Hypertension	279 (28.3)	121 (24.7)	158 (31.9)	0.01
MI	277 (28.1)	117 (23.9)	160 (32.3)	0.004
Cardiac arrest	275 (27.9)	144 (29.4)	131 (26.4)	0.29
Congestive heart failure	261 (26.5)	95 (19.4)	166 (33.5)	<0.001
Syncope	186 (18.9)	99 (20.2)	87 (17.5)	0.28
AF	157 (15.9)	61 (12.5)	96 (19.4)	0.003
Valve disease	120 (12.2)	72 (14.7)	48 (9.7)	0.02
Diabetes	111 (11.3)	42 (8.6)	69 (13.9)	0.008
Kidney disease	81 (8.2)	36 (7.4)	45 (9.1)	0.33
Stroke (including TIA)	51 (5.2)	21 (4.3)	30 (6.0)	0.21
COPD	49 (5.0)	18 (3.7)	31 (6.3)	0.06



- S-ICD fulfils predefined endpoints for safety and efficacy.
- Midterm performance rates on complications, inappropriate shocks, and conversion efficacy were comparable to rates observed in TV-ICD.

Boersma L, et al. JACC 2017

Real-World Clinical Experience of SICD
EFFORTLESS Registry



Description	Events	Patients	% of Patients
Infection requiring device removal	27	24	2.4
Erosion	17	17	1.7
Inappropriate shock: oversensing	12	11	1.1
Other procedural complications	13	10	1.0
Hematoma	9	9	0.9
Discomfort	8	8	0.8
Suboptimal electrode position	7	7	0.7
Electrode movement	7	7	0.7
Premature battery depletion	5	5	0.5
PG movement	6	5	0.5
Unable to convert during procedure	6	5	0.5
Incision/superficial infection	5	5	0.5
Other technical complications	4	4	0.4
Suboptimal PG and electrode position	3	3	0.3
Inability to communicate with the device	3	3	0.3
Inappropriate shock: SVT above discrimination zone (normal device function)	2	2	0.2
Suboptimal pulse generator position	1	1	0.1
Total	135	115	11.7

Boersma L, et al. JACC 2017

PRAETORIAN Trial

Class I/IIa Indication for ICD
No pacing indication

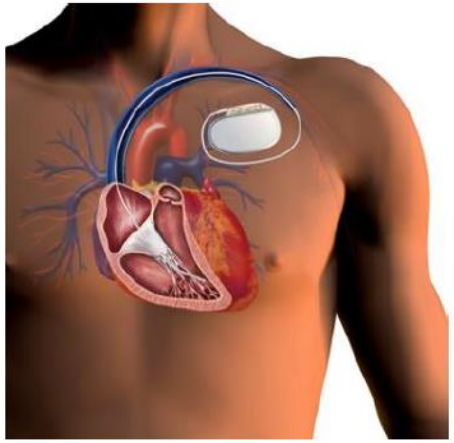
n=849

S-ICD
n=426

TV-ICD
n=423

Median FU 48 months

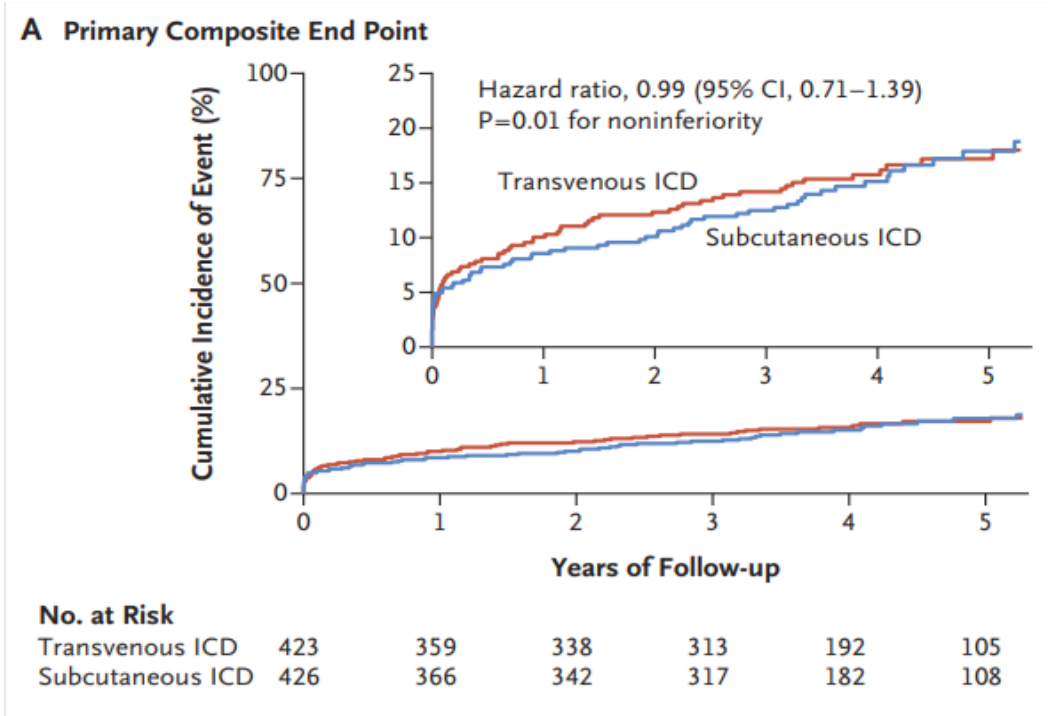
Primary Endpoints:
Device-related complication and Inappropriate shock

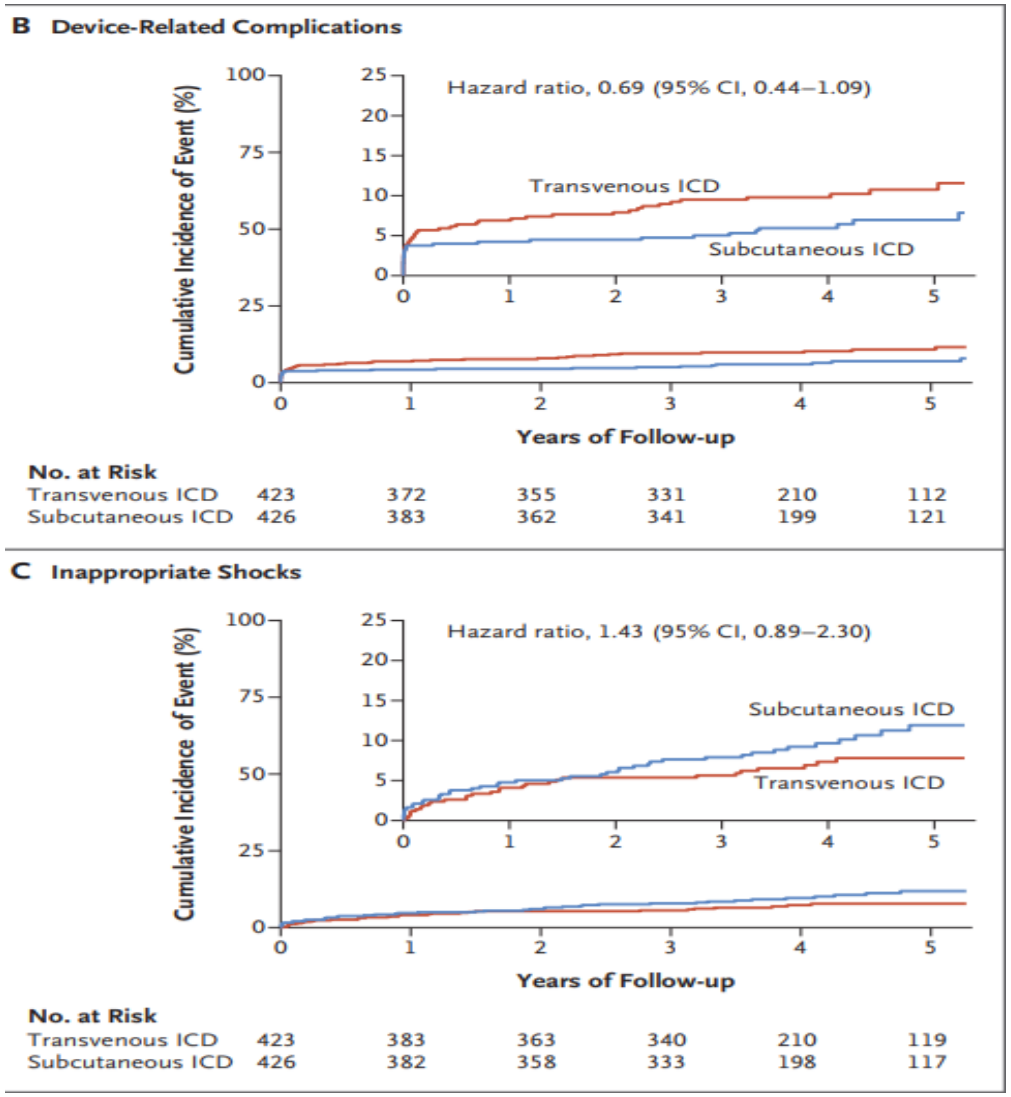


- ✓ Classical ICD population
- ✓ Composite Endpoint (Device related complications+ IAS)
- ✓ RCT
- ✓ Secondary endpoints:
  - ✓ IAS
  - ✓ Device related complications
  - ✓ Death from any cause
  - ✓ Appropriate ICD therapy (including antitachycardia pacing)
  - ✓ Major adverse cardiac events
  - ✓ Hospitalization for heart failure
  - ✓ Crossover between the assigned devices.

Knops R. et al., Heart Rhythm Society Late Breaking Clinical Trials 2020

PRAETORIAN Trial





-In patients with an indication for an ICD but no indication for pacing, the subcutaneous ICD was non-inferior to the TV- ICD with respect to device related complications and inappropriate shocks

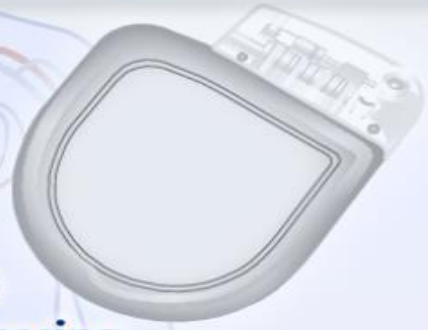
Knops RE, et al. NEJM 2020

PRAETORIAN Trial

Subcutaneous or Transvenous Defibrillator Therapy

MULTICENTER, RANDOMIZED, NONINFERIORITY TRIAL

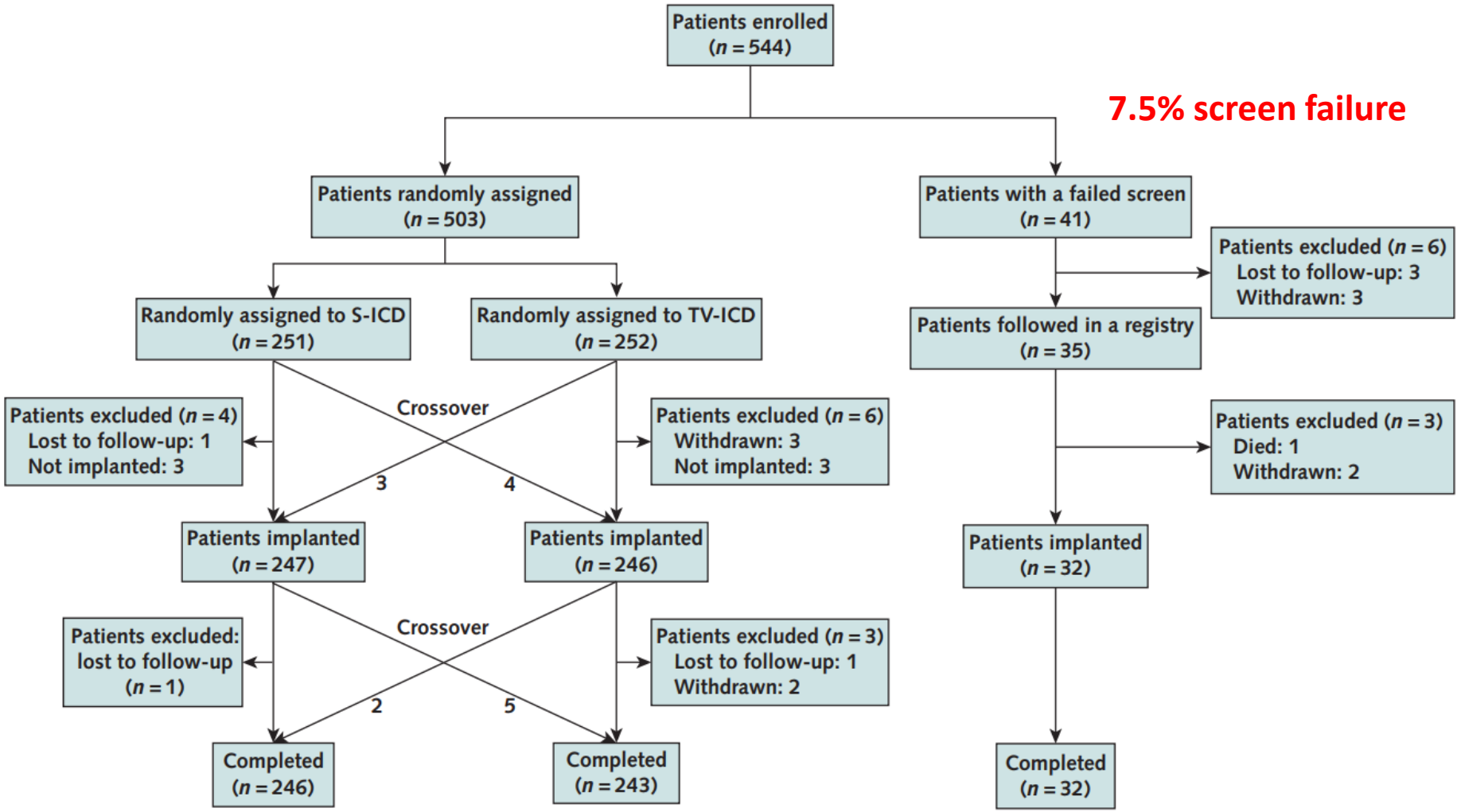
849
Patients with an indication for ICD therapy but not for pacing



	Subcutaneous ICD (N=426)	Transvenous ICD (N=423)
Composite of device-related complications and inappropriate shocks	68 patients	68 patients
	HR, 0.99; 95% CI, 0.71 to 1.39; noninferiority margin, 1.45; P=0.01 for noninferiority	
Device-related complications	31 patients	44 patients
	HR, 0.69; 95% CI, 0.44 to 1.09	
Inappropriate shocks	41 patients	29 patients
	HR, 1.43; 95% CI, 0.89 to 2.30	

Knops RE, et al. NEJM 2020

Avoid Transvenous Leads in Appropriate Subjects (ATLAS)



Healey JS, et al. Ann Intern Med 2022

Avoid Transvenous Leads in Appropriate Subjects (ATLAS)

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

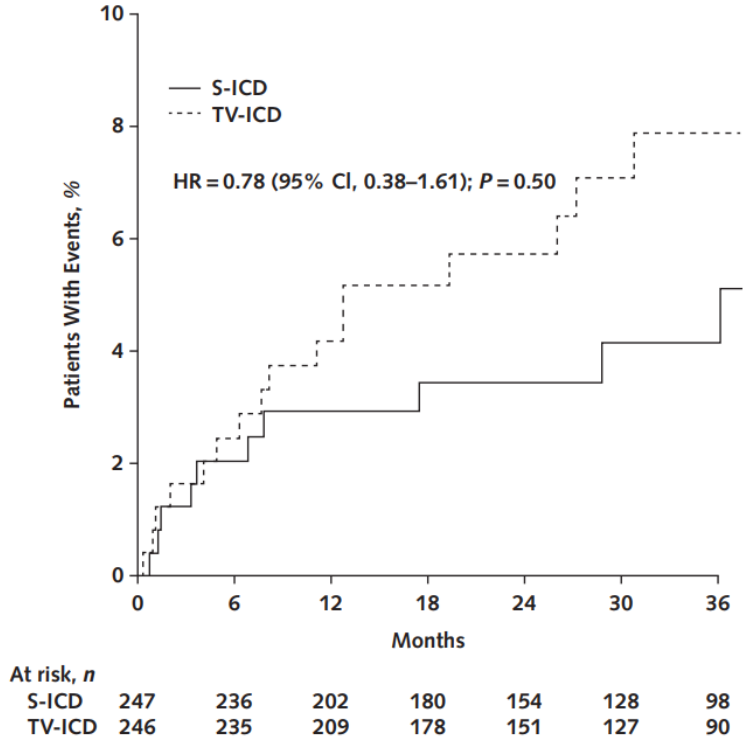
Characteristics	Randomly Assigned (*n* = 503)	S-ICD (*n* = 251)	TV-ICD (*n* = 252)
Mean age (SD), *y*	49 (11.5)	48 (11.9)	50 (11.1)
Secondary prevention indication	137 (27.2)	72 (28.7)	65 (25.8)
Previous sustained ventricular tachycardia, *n (%)*	46 (9.1)	23 (9.2)	23 (9.1)
Previous cardiac arrest, *n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

ICD = implantable cardioverter defibrillator; S-ICD = subcutaneous implantable cardioverter defibrillator; TV-ICD = transvenous implantable cardioverter defibrillator.

Healey JS, et al. Ann Intern Med 2022

Avoid Transvenous Leads in Appropriate Subjects (ATLAS)

Outcomes	S-ICD (*n* = 251)	TV-ICD (*n* = 252)	Risk Difference (95% CI)
Primary safety 6-mo outcome, *n* (%)	1 (0.4)	12 (4.8)	−4.4 (−6.9 to −1.9)
Hemothorax or pneumothorax	0 (0)	2 (0.8)	-
Cardiac perforation, tamponade, pericardial effusion, or pericarditis	1 (0.4)	4 (1.6)	-
Lead dislodgement or loss of sensing or pacing requiring revision	0 (0)	2 (0.8)	-
New moderate-severe or severe tricuspid insufficiency	0 (0)	3 (1.2)	-
Ipsilateral upper extremity deep venous thrombosis	0 (0)	1 (0.4)	-
Secondary safety 6-mo composite, *n* (%)	11 (4.4)	14 (5.6)	−1.2 (−2.4 to 0.1)
Device-related infection requiring surgery	2 (0.8)	1 (0.4)	-
ICD wound hematoma	3 (1.2)	1 (0.4)	-
Myocardial infarction	2 (0.8)	0 (0)	-
Stroke or transient ischemic attack	1 (0.4)	0 (0)	-
Death	3 (1.2)	0 (0)	-
Postoperative pain on 10-point numeric rating scale, LS mean (95% CI)*			
At ICD implant	4.2 (4.0 to 4.4)	2.9 (2.6 to 3.1)	1.3 (1.0 to 1.7)
At 1 mo	1.3 (1.1 to 1.5)	0.9 (0.7 to 1.2)	0.4 (0 to 0.7)
At 6 mo	0.7 (0.4 to 0.9)	0.5 (0.2 to 0.7)	0.2 (0 to 0.6)
Any inappropriate shock (any time),† *n* (%)	16 (6.4)	7 (2.8)	3.6 (1.4 to 5.8)
T-wave oversensing	6	0	-
Electromagnetic interference‡	6	2	-
Myopotentials	2	0	-
Atrial arrhythmia	2	5	-

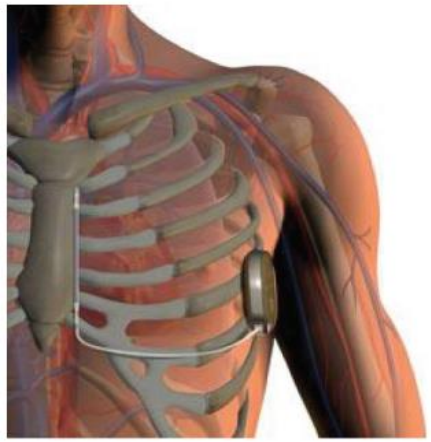


- S-ICD reduces perioperative lead-related complications without significantly compromising the effectiveness of ICD shocks, but with more early postoperative pain and a trend for more inappropriate shocks.

Healey JS, et al. Ann Intern Med 2022

Clinical Applications of S-ICD

Guidelines Indications



Should be considered (IIa)

Bradycardia support, CRT or ATP is not needed

May be considered (IIb)

Venous access is difficult
After the removal of a transvenous ICD for infections
Young patients with a long-term need for ICD therapy

Tailoring Approach

- Adequate S-ICD screening at rest or during stress
- Progressive nature of the underlying disease
- Infective risk
- VT susceptibility
- Work activity
- Sport activity
- Psychosocial issues

Advantages

- Safe implantation technique
- No needs for fluoroscopy
- Absence of intravascular leads
- Less systemic infections
- Cosmetic anatomical location
- Well tollerated

Drawbacks

- Need of pre-implantation screening
- No pacing or ATP capability
- No remote monitoring
- No arrhythmias monitoring
- Pulse generator larger than TV-ICD
- Battery life lower than TV-ICD
- High costs

Russo V, et al. Expert Review of Cardiovascular Therapy 2023

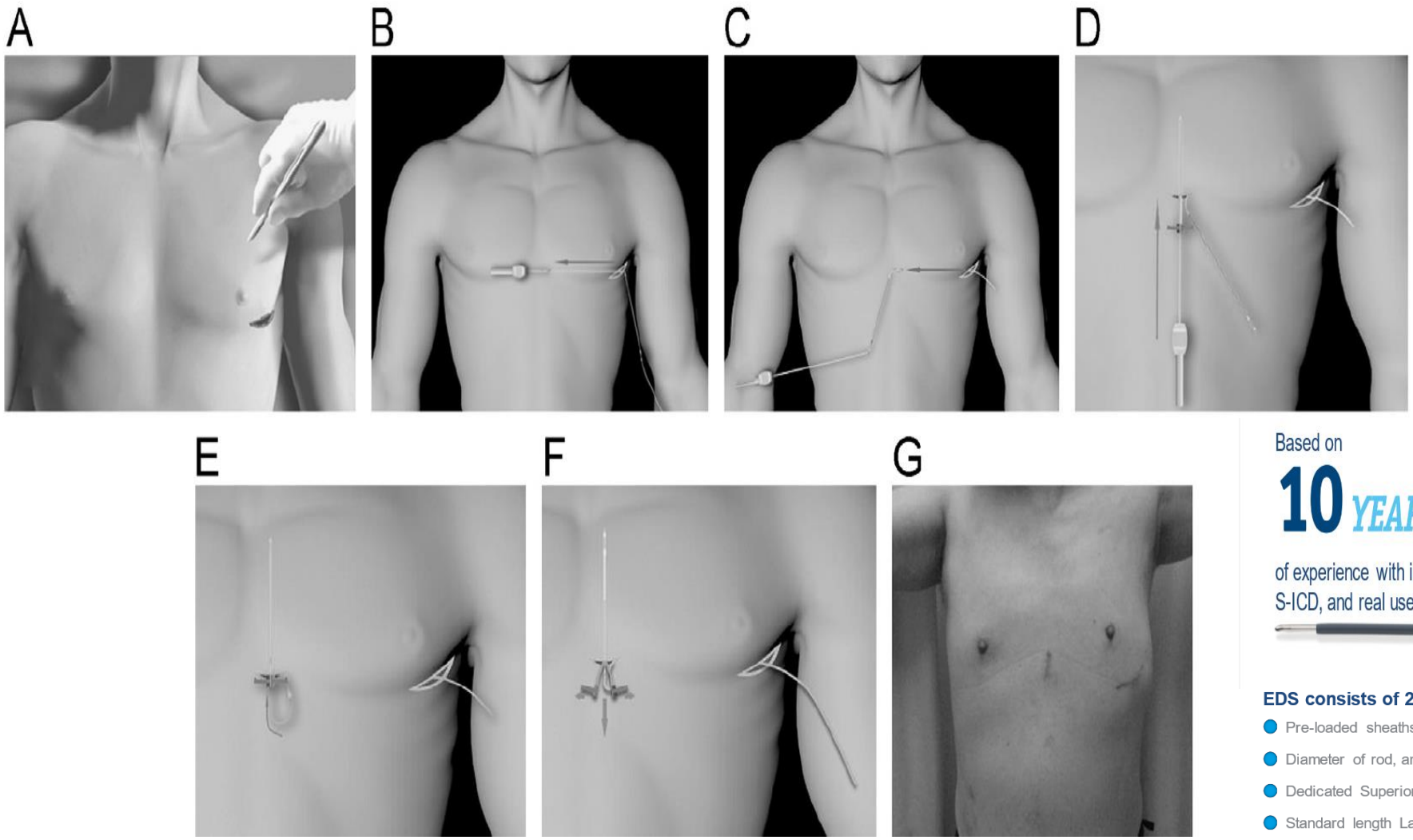
Outlines

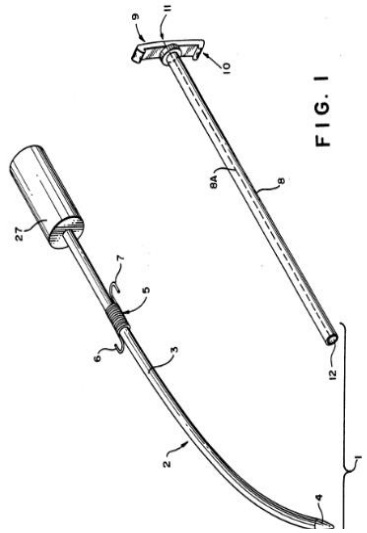
1. Safety and Efficacy of S-ICD

2. **Implantation of S-ICD**
   - **Lead and Device Implant**
   - **Anesthetic method**
   - **Device Replacement**

3. Future Perspective of S-ICD

Two Incisions Technique for S-ICD



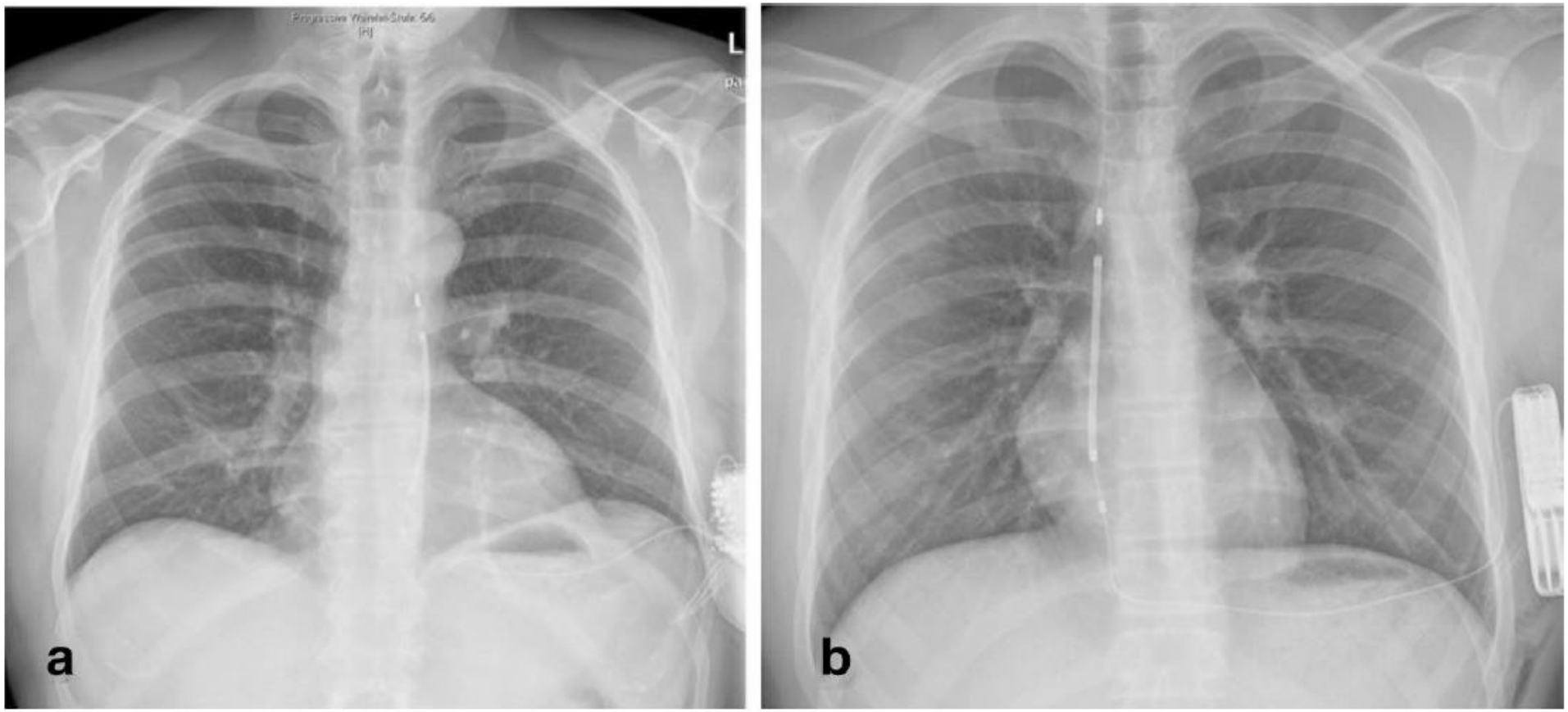


EDS consists of 2 Tunnelling Tools with pre-loaded sheaths:

- Pre-loaded sheaths are appropriately sized for Tunnelling Tool length
- Diameter of rod, and tapering at end of sheath is designed to prevent sheath kinking
- Dedicated Superior Tunnelling Tool for 2-incision technique (pre-loaded 14 cm sheath)
- Standard length Lateral Tunnelling Tool for sheath delivery of electrode (pre-loaded 21 cm sheath)

Knops RE, et al. Heart Rhythm 2013

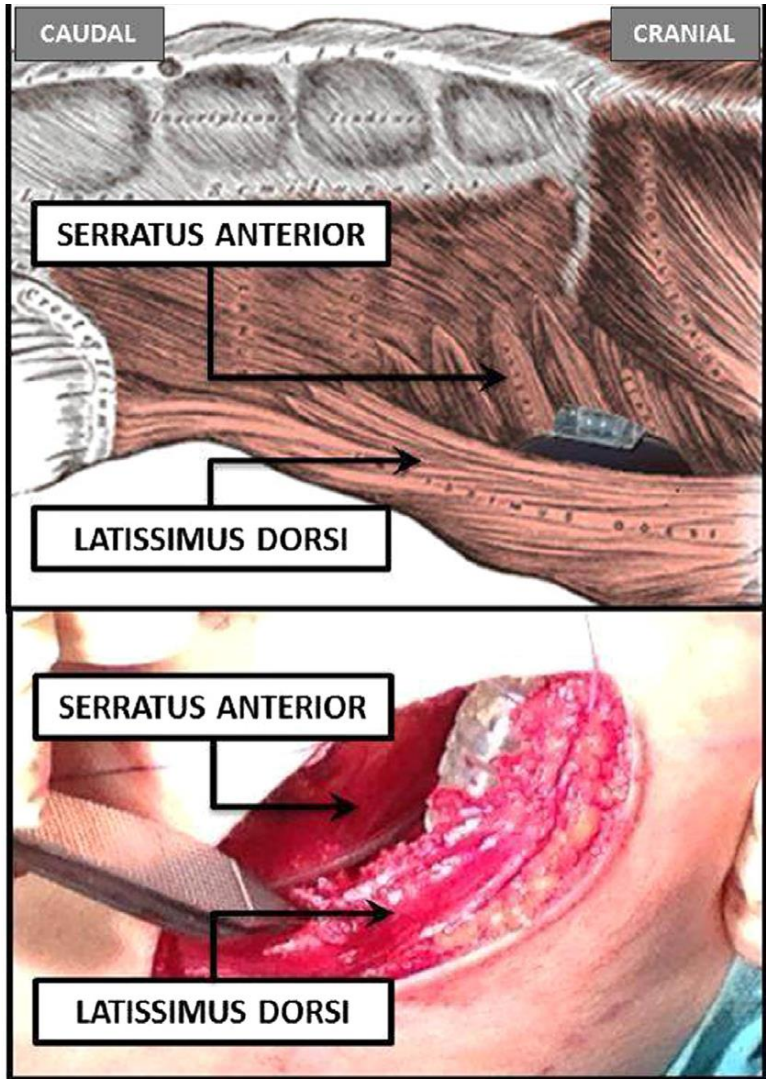
Right vs Left Implant of S-ICD



- Right-sided electrode implant might be an alternative if a left-sided electrode implant is inadequate.
- It might also be favorable for young patients with narrow heart silhouettes in the midsagittal position, eg Asian pts.

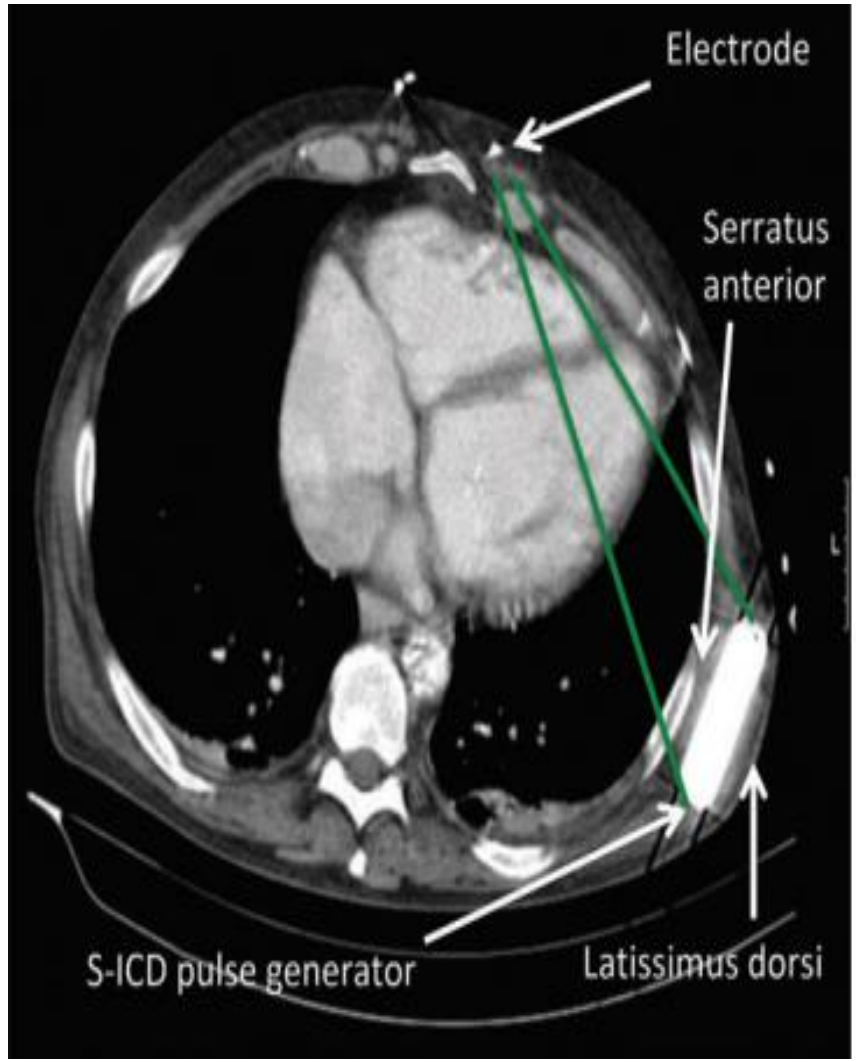
Bettin M, Clinical Res Cardiol 2018

Sub-muscular Technique for S-ICD



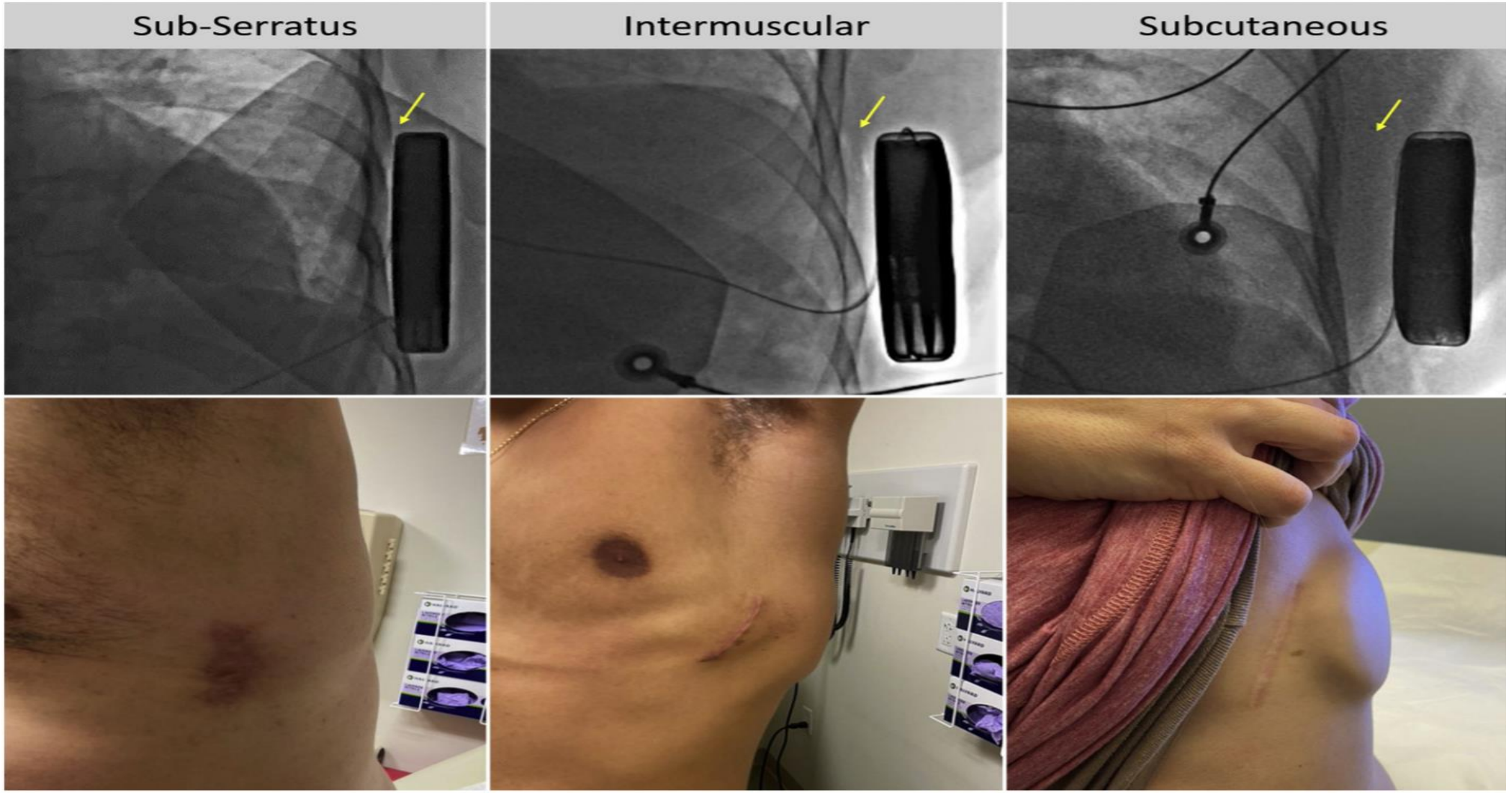
Ferrari P, et al. J Arrhythm 2016

Courtesy of Stephen O'Connor, PhD



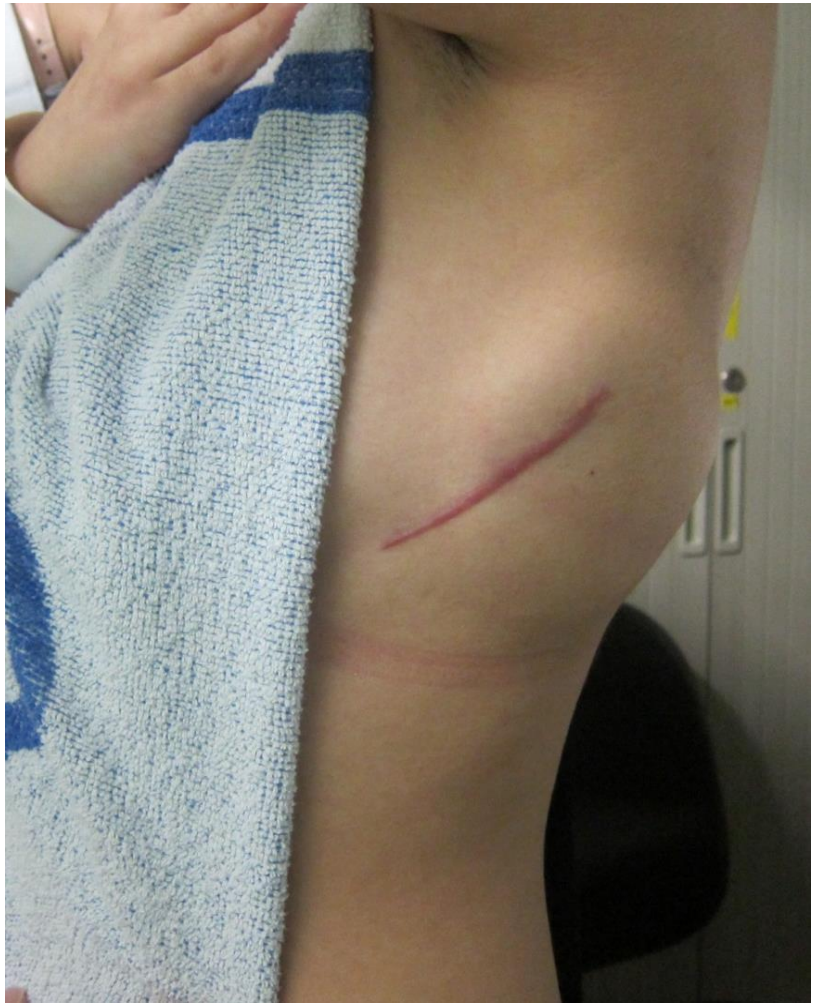
Winter J et al, Europace 2016

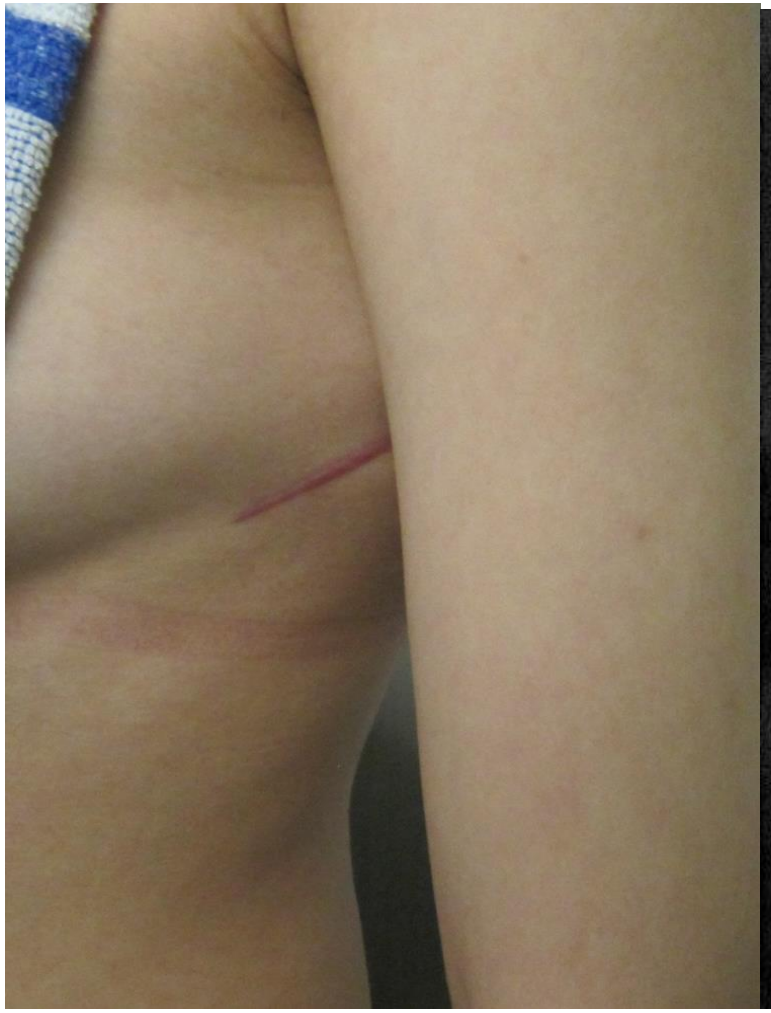
Sub-serratus Implantation of S-ICD

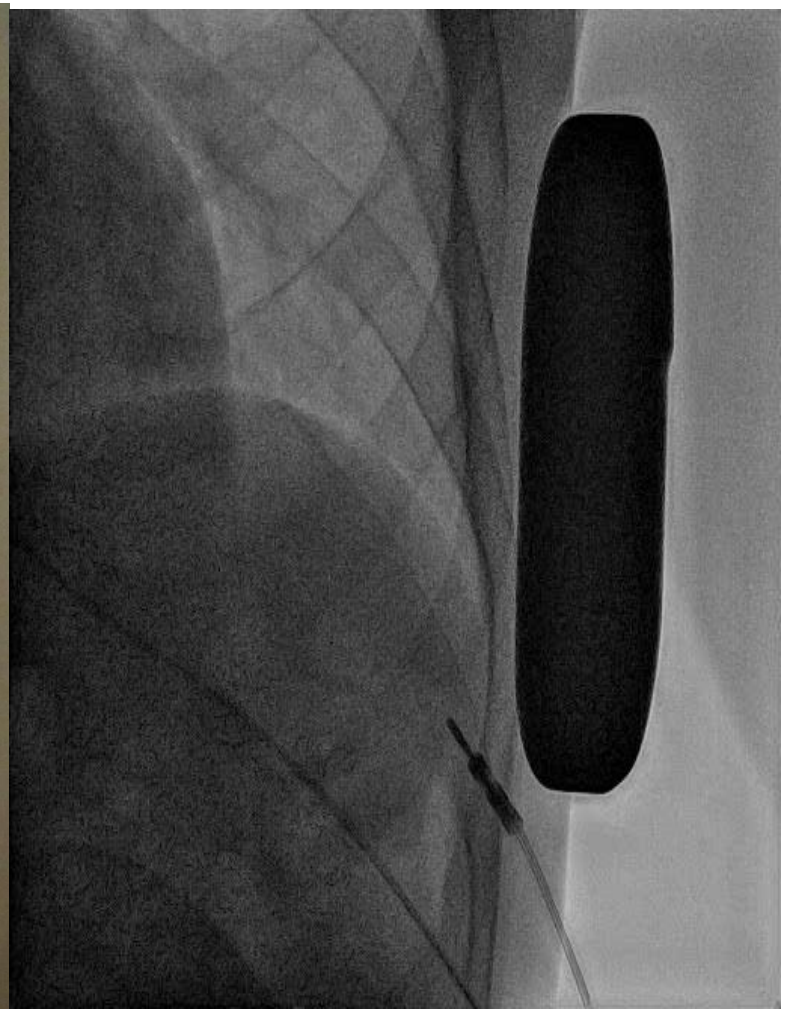


Smietana J, et al. Heart Rhythm 2021

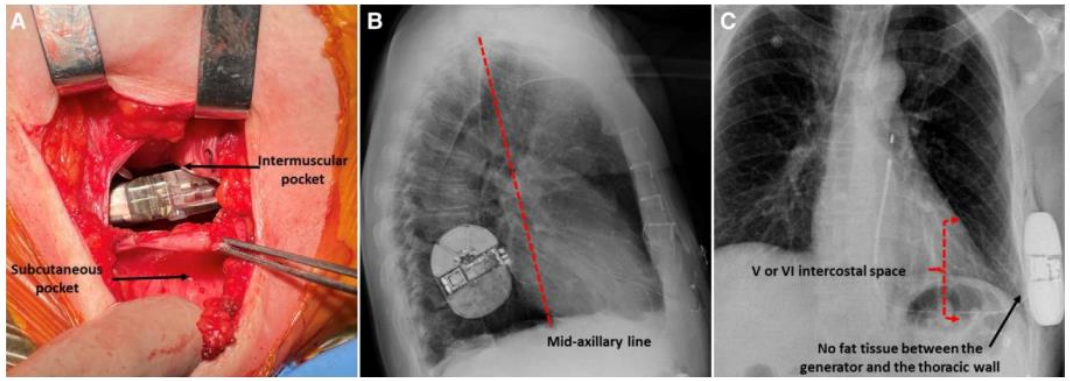
Implant Procedure Experiences in QMH

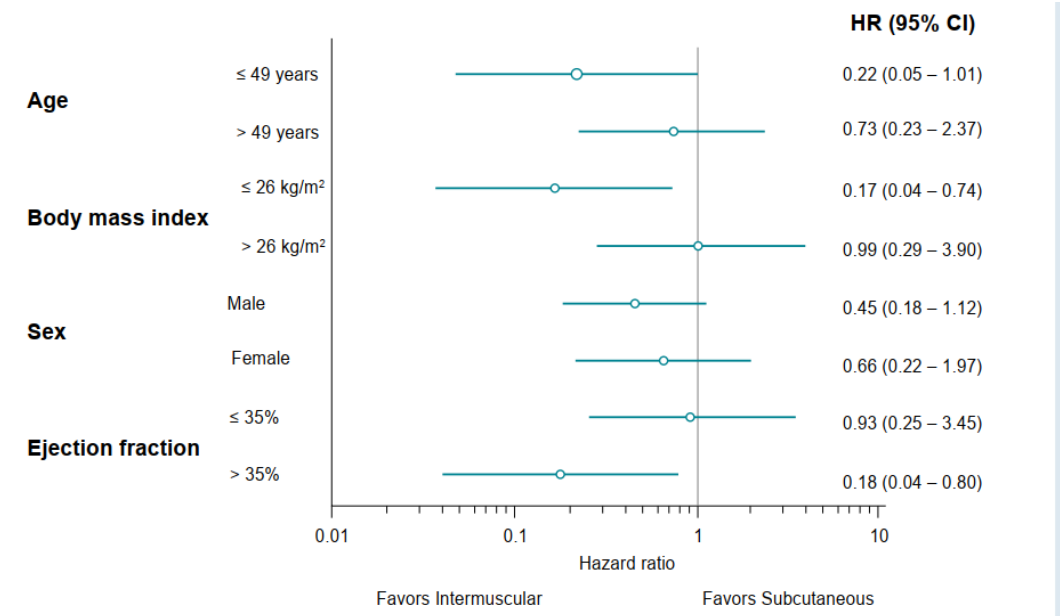


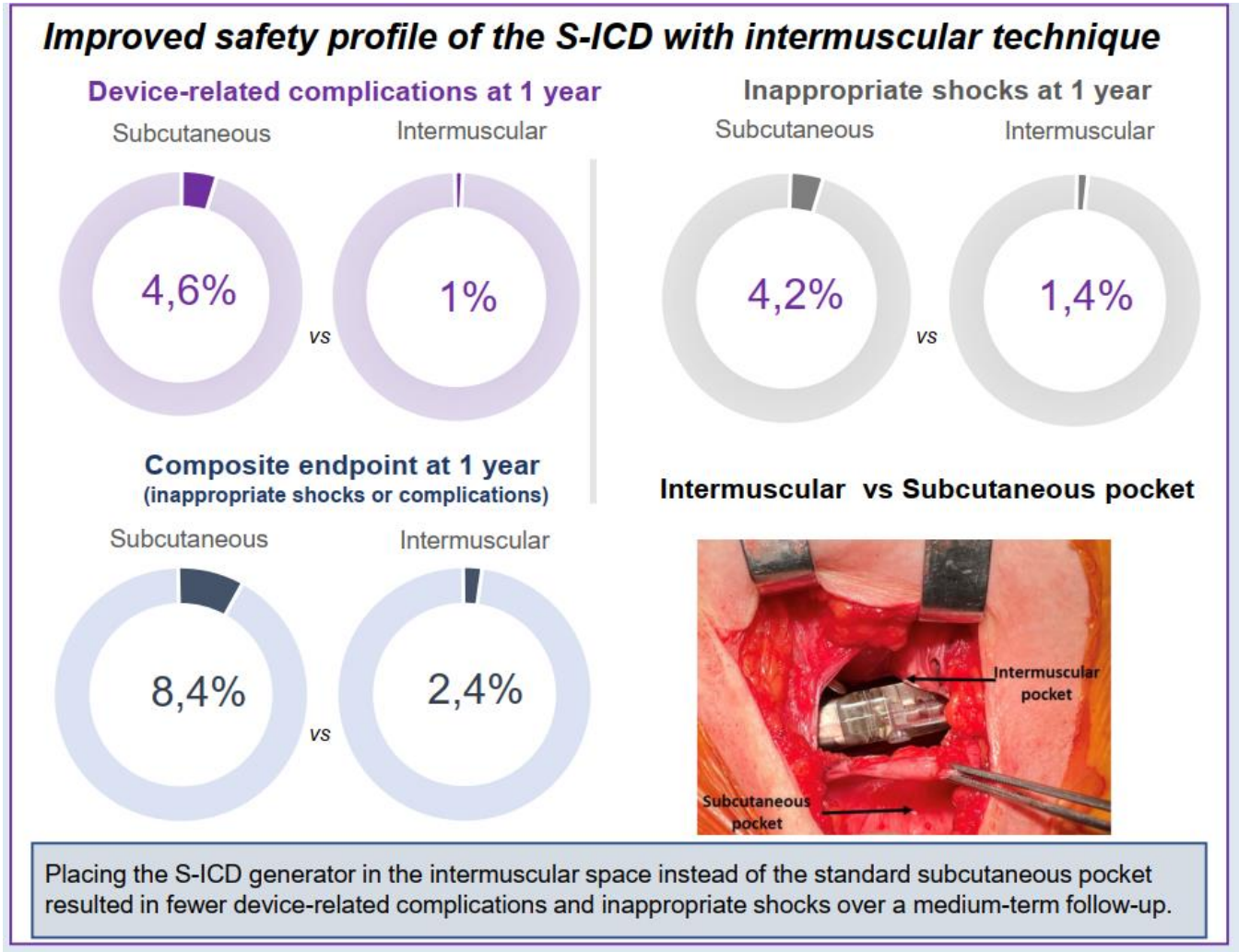




Sub-muscular Technique for S-ICD



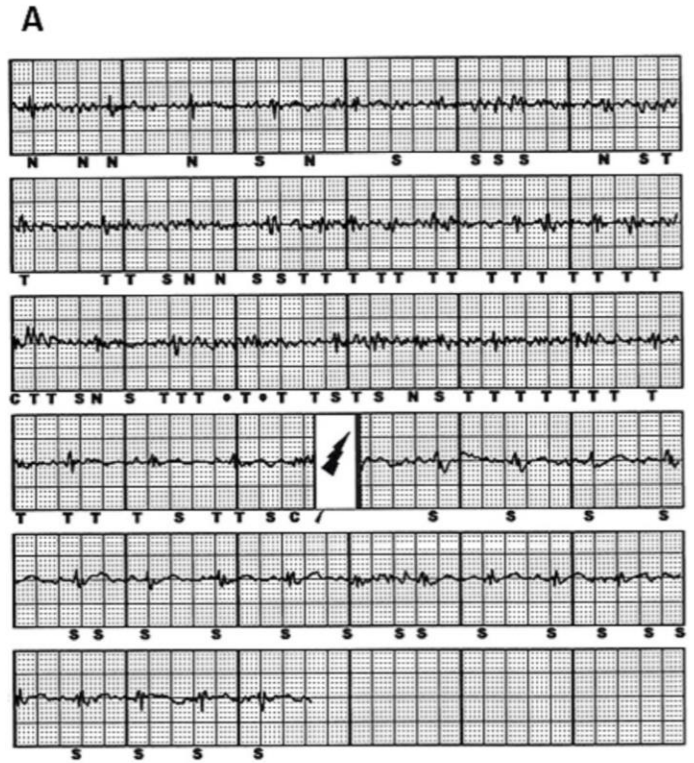


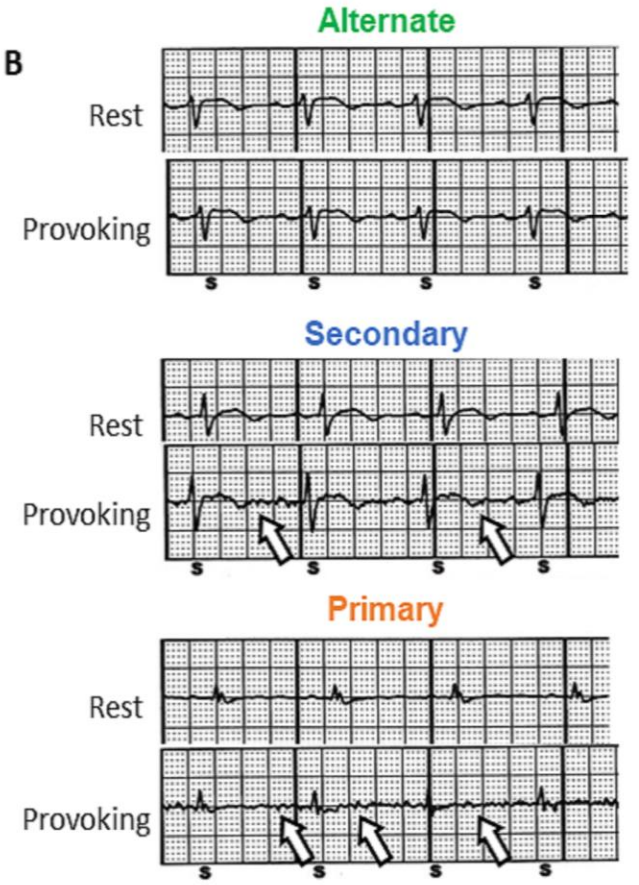


Botto GL et al, Europace 2023

Inappropriate Shock in SICD due to Myopotential Oversensing

	All	Non-shock	Appropriate shock	IAS, all causes	IAS, myopotential-induced
n	61	49	7	6	4
Age	48 ± 17	46 ± 17	52 ± 12	51 ± 18	49 ± 16
Male	54 (88%)	45 (87%)	6 (86%)	100%	100%
Follow-up period	732 ± 422	752 ± 360	918 ± 322	891 ± 353	891 ± 353
Day from implantation to the first shock	N/A	N/A	117 ± 107	436 ± 312	304 ± 185
Primary prevention	28 (46%)	24 (46%)	3 (43%)	3 (50%)	3 (75%)
Height (cm)	168 ± 8	167 ± 8	172 ± 8	171 ± 5	171 ± 6
Body weight (kg)	69 ± 16	69 ± 17	66 ± 13	71 ± 9	69 ± 7
Body mass index	24.1 ± 4.8	24.4 ± 5.0	22.2 ± 3.3	24.3 ± 3.9	23.3 ± 3.8
Right-sided lead position	6 (10%)	2 (4%)	2 (28%)	3 (50%)	3 (75%)
LVEF (%)	48 ± 22	46 ± 22	58 ± 19	53 ± 21	56 ± 24
Channelopathies*	20 (33%)	17 (33%)	3 (43%)	3 (50%)	2 (50%)
IHD	15 (25%)	13 (25%)	0	1 (17%)	0
DCM	12 (20%)	12 (23%)	1 (14%)	1 (17%)	1 (25%)
HCM	6 (10%)	5 (10%)	1 (14%)	1 (17%)	1 (25%)
VSA-related VT/VF	5 (8%)	4 (8%)	2 (28%)	0	0





- **Myopotential over-sensing after SICD**
  - **Account for 2/3 of inappropriate shock**
  - **More common in male after R sided lead implantation**

Tsutsui K, et al. Int Heart J 2020

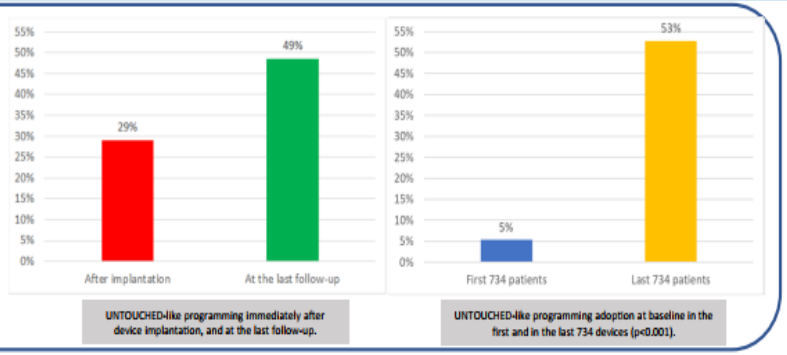
Programming to Reduce Inappropriate Shock in SICD

Could the incidence of inappropriate shocks in S-ICD patients be reduced by adequate device programming in clinical practice?

The standardized programming proposed by the UNTOUCHED- study programming is:

- conditional zone cut-off between 200 and 250 bpm
- shock zone cut-off at 250 bpm.

In clinical practice, there has been a trend in recent years towards the wider adoption of optimized programming.

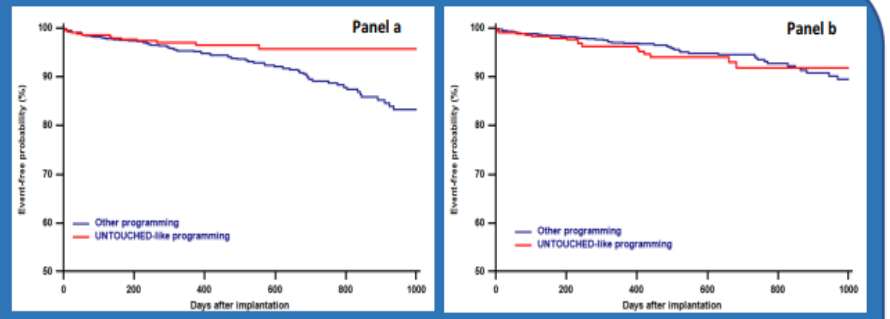


UNTOUCHED-like programming immediately after device implantation, and at the last follow-up.

UNTOUCHED-like programming adoption at baseline in the first and in the last 734 devices (p<0.001).

The "UNTOUCHED-like" programming, with high-rate cut-offs for discrimination, reduced the rate of inappropriate shock in the S-ICD population, without affecting therapy effectiveness.

The rate of inappropriate shocks at one year was 3.0% with and 4.6% without UNTOUCHED-like programming.



Kaplan-Meier analysis of time to first inappropriate shock (Panel a) (HR 0.47, 95%CI 0.30–0.75, p=0.010) and to first appropriate shock (Panel b) (HR 0.98, 95%CI 0.59–1.61, p=0.925)

Table 2 Causes of inappropriate shocks

	Number of patients (%)	Reaction (number of patients)
Inappropriate Shock Therapy	103 (7.0)	
– Noise from entrapped subcutaneous air	11 (0.7)	Solved without action (11)
– Atrial fibrillation or supraventricular tachycardia	18 (1.2)	Reprogramming (10); Change in medication [a] (6); Atrial fibrillation ablation (1); Atrial fibrillation ablation after change in medication (1)
– T-Wave oversensing	20 (1.4)	Reprogramming (19); Explantation after Reprogramming (1)
– Other cardiac oversensing	15 (1.0)	Reprogramming (14); Explantation after Reprogramming (1)
– Non-cardiac oversensing	39 (2.7)	Reprogramming (37); Explantation (2 [b])

Rordorf R, et al, Europace 2023

Anesthesia for S-ICD

Historically S-ICD has mainly been implanted under General Anaesthesia:

Study	GA
EFFORTLESS[25]	**60%**
Post Approval Study[33]	**64%**

Various anaesthesia options have been reported in literature:

- **General Anaesthesia (GA)** – fully supported by anaesthesiologist, patient is intubated.
- **Monitored Anaesthesia Care (MAC)** – may require anaesthesiologist in room; "MAC represents a continuum of anesthesia care, from the awake-state to potentially general anaesthesia without intubation"[102].
- **Regional Anaesthesia (RA)** – ultrasound guided thoracic block e.g. serratus plane block[103,104].
- **Minimalist Approach (MA)** - IV sedation/analgesia supplemented with local anaesthesia. Sedation and airway management directed by electrophysiologist and lab staff[5,105].

LA/Sedation for S-ICD

Table 3 Procedural characteristics and pain assessments

Total procedure duration (min)	112 ± 20
Implantation duration (min)	51 ± 14
Drug administrated	
- Midazolam (mg/kg)	0.11 ± 0.03
- Nalbuphine (mg/kg)	0.27 ± 0.05
- Flumazenil (mg)	0.6
Ramsay score	4.5
Time from sedation initiation to:	
- Pocket creation (min)	46 ± 7
- Lead tunneling A (min)	53 ± 7
- Lead tunneling B (min)	59 ± 7
Pain assessment	
- CPOT pocket creation	1.3 ± 1.8
- CPOT lead tunneling A	1.2 ± 1.4
- CPOT lead tunneling B	1.7 ± 1.4
Procedural pain recollection	
- NRS after patient recovery	0.8 ± 1.6
Successful defibrillation at first 65 J attempt (%)	15 (93.8)
Shock impedance (Ohms)	74
Dual zone programming (%)	12 (75)

Lead tunneling A (lateral wound to the parasternal incision); Lead tunneling B (along the sternal border)

CPOT Critical-Care Pain Observation Tool, *NRS* Numeric Rate Scale

Table 2 Patient characteristics, total administrated dose (mg/kg) of midazolam and nalbuphine, Ramsay score, CPOT and NRS scores, and defibrillation shocks delivered

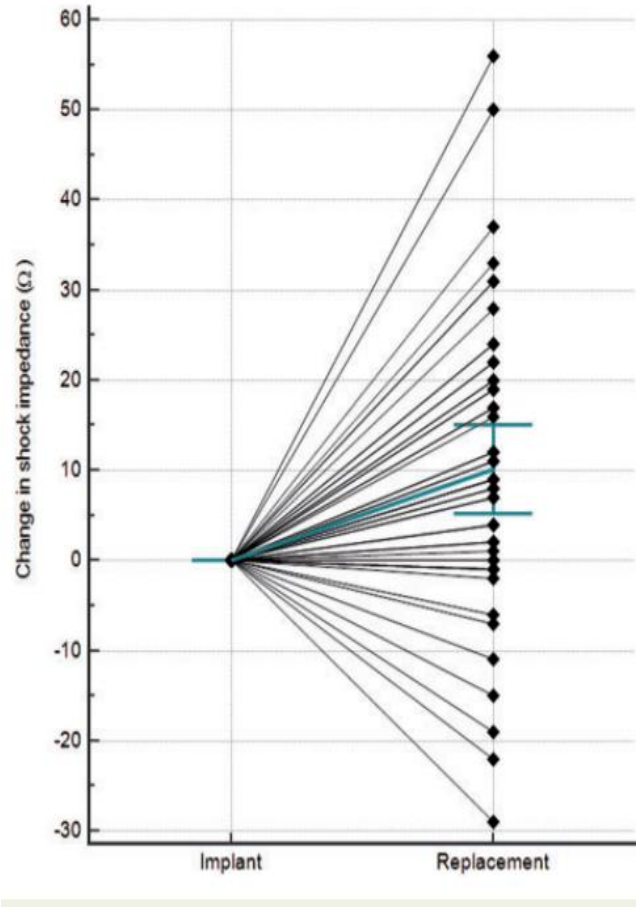
Patient	Gender	Age	Midazolam dose (mg/kg)	Nalbuphine dose (mg/kg)	Ramsay score	CPOT score			Number of defibrillation shocks	NRS score
						Pocket creation	Lead tunneling A	Lead tunneling B		
1[a]	M	45	0.15	0.30	4	2	1	2	2	0
2	F	38	0.12	0.30	5	1	0	1	1	4
3	M	35	0.14	0.29	5	0	0	0	1	0
4	M	59	0.08	0.30	5	1	2	2	1	0
5	M	60	0.15	0.30	4	7	5	5	1	0
6	F	57	0.06	0.22	5	0	0	0	1	0
7	M	71	0.09	0.30	5	0	0	0	1	0
8	M	68	0.14	0.28	4	2	3	3	1	0
9	F	65	0.14	0.23	4	3	0	1	1	0
10	M	63	0.04	0.14	4	0	0	1	1	0
11	M	42	0.13	0.29	5	0	0	0	1	0
12	F	55	0.13	0.30	5	0	2	2	1	4
13	M	40	0.14	0.30	5	2	1	3	1	0
14	F	57	0.15	0.30	4	1	2	2	1	3
15	M	59	0.09	0.30	4	0	1	2	1	0
16	M	53	0.09	0.20	4	3	3	3	1	0

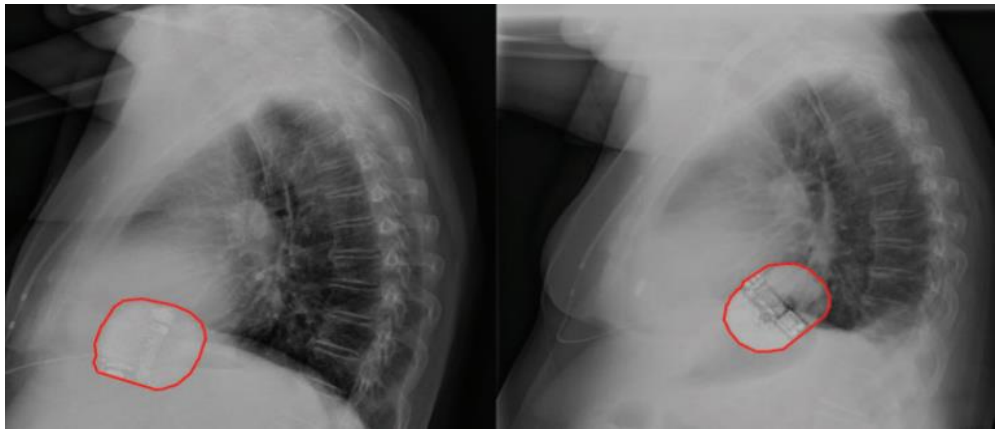
CPOT Critical-Care Pain Observation Tool, *NRS* Numeric Rate Scale

- Operator-guided controlled sedation with midazolam and analgesia with nalbuphine is effective to alleviate procedural pain in patients undergoing S-ICD implantation

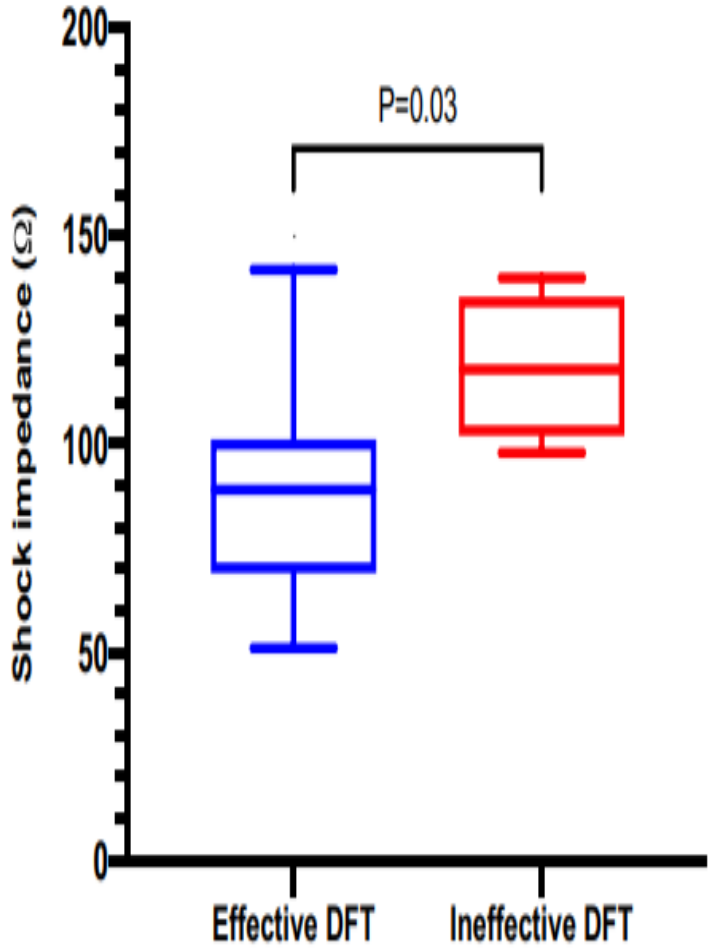
Peyrol M, et al. J Interv Card Electrophysiol 2017

Device Replacement for S-ICD





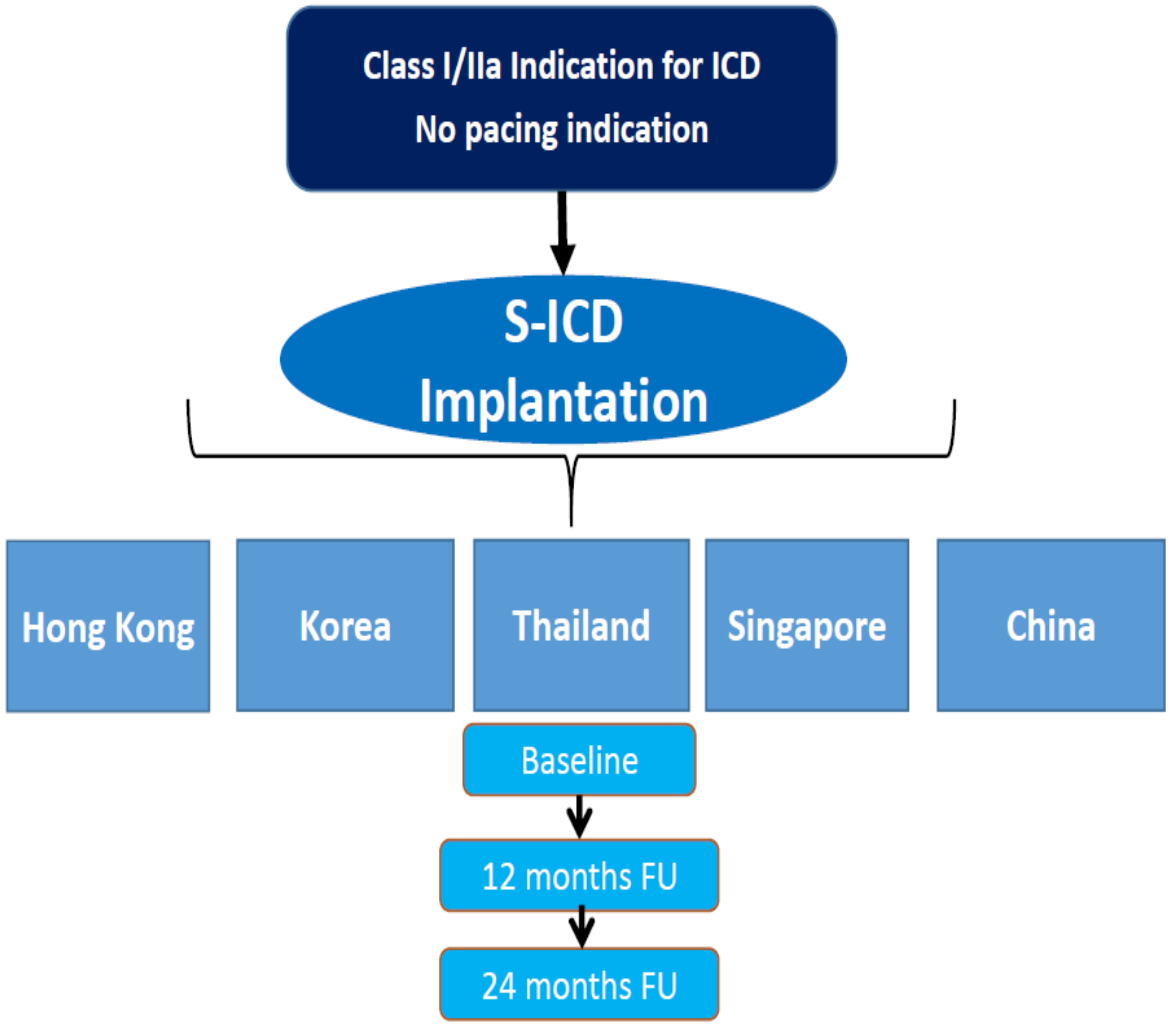
- No procedure-related complications after elective (S-ICD) replacement, and an overall complication rate of 1.4% per year.
- High voltage impedance increases over time = need for DFT testing during replacement
- ? PRAETORIAN score might be a useful tool to determine the need for repositioning during S-ICD replacement, in order to minimize defibrillation threshold and ensure successful defibrillation.



Van der Stiojt W, et al. Europace 2021

Rudic B, et al. Heart Rhythm 2020

S-ICD: First Asian Registry

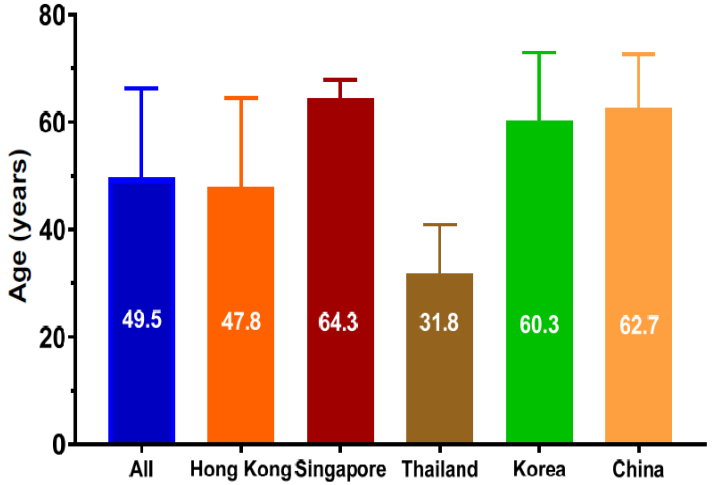


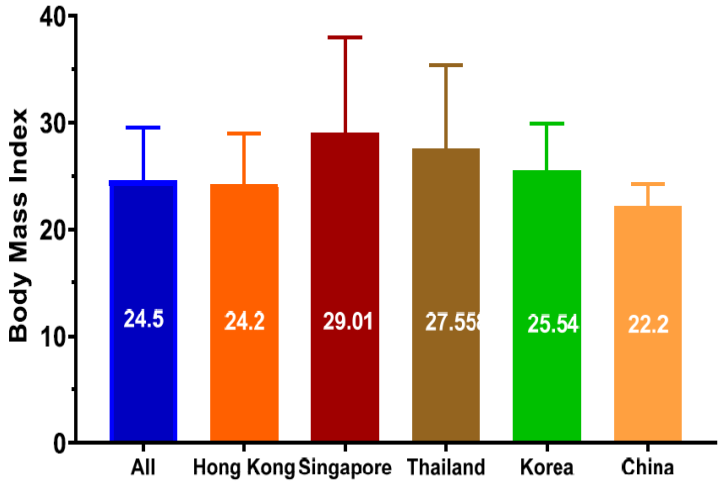
Clinical Characteristics	
Age (yrs)	49.6±16
Male (%)	72
BMI	24.6±4.9
LVEF (%)	44±15
Indications: Primary Secondary	 20 (27%) 55 (73%)
Procedure: New implant Replacement	 70 (93%) 5 (7%)

Etiologies	Numbers (%)
Ischemic CMP	28 (37%)
Non-ischemic CMP	17 (23%)
LQTs	2 (3%)
ARVD	3 (4%)
Idiopathic VF	12 (16%)
Brugada syndrome	7 (9%)
HOCM	5 (7%)
Other (ACHD)	1 (1%)

Tse HF, et al. APHRS 2021

S-ICD: First Asian Registry





Parameters	Numbers (%)
Procedural duration (mins)	74±27
DFT testing	60 (80%)
Type of anaesthesia GA MAC LA + sedation	 8 (11%) 4 (5%) 63 (84%)
Shock impedance (ohm)	76±21
Device/lead repositioning	2 (3%)
Submuscular implant	60 (80%)
Acute procedural success	75 (100%)
Acute complication	0 (0%)

Tse HF, et al. APHRS 2021

S-ICD: First Asian Registry

Results: Safety and Efficacy

Parameters	1 Mth FU	1 Yr FU
ICD shock	0	2 (2.7%)
Appropriate shock	0	1 (1.3%)
Inappropriate shock	0	1 (1.3%) Myopotential noise sensing
Lead related complications	1 (1.3%) Lead failure needed replacement	1 (1.3%) Lead failure needed replacement
Pocket complications	0	0
Infection	0	1 (1.3%) Lead infection needed removal
Overall major adverse event	1 (1.3%)	3 (4%)

Tse HF, et al. APHRS 2021

Outlines

1. Safety and Efficacy of S-ICD
2. Implantation of S-ICD
   - Lead and Device Implant
   - Anesthetic method
   - Device Replacement
3. **Future Perspective of S-ICD**

Evolution of S-ICD Therapy

The S-ICD has gone through rapid and incremental refinements in technology

2002 — 2009 — 2012 — 2015 — 2016 — 2017

1st Generation

2nd Generation

- Smaller, thinner, longer-lasting device*
- LATITUDE™ compatible[1]

3rd Generation

- SMART Pass[1]
- MRI compatible[1**]
- AF Monitor™ [1]
- New Electrode,
- Electrode Delivery System (EDS)
- 2 Incision labelling

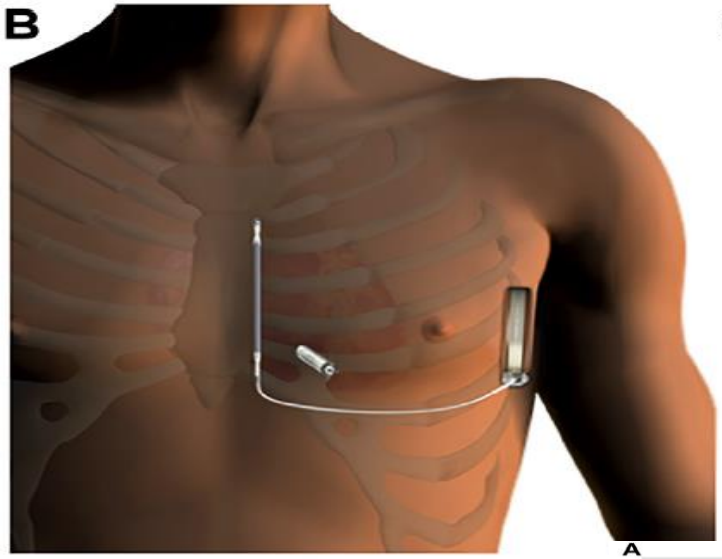
Automated Screening Tool

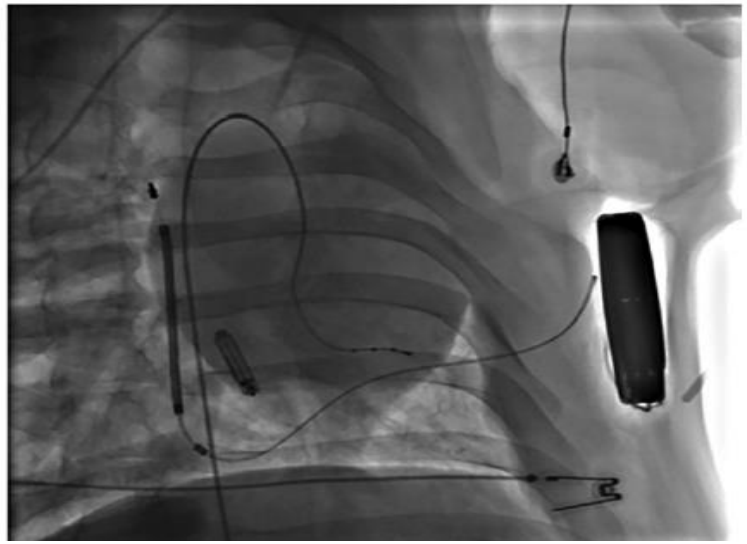
Future developments

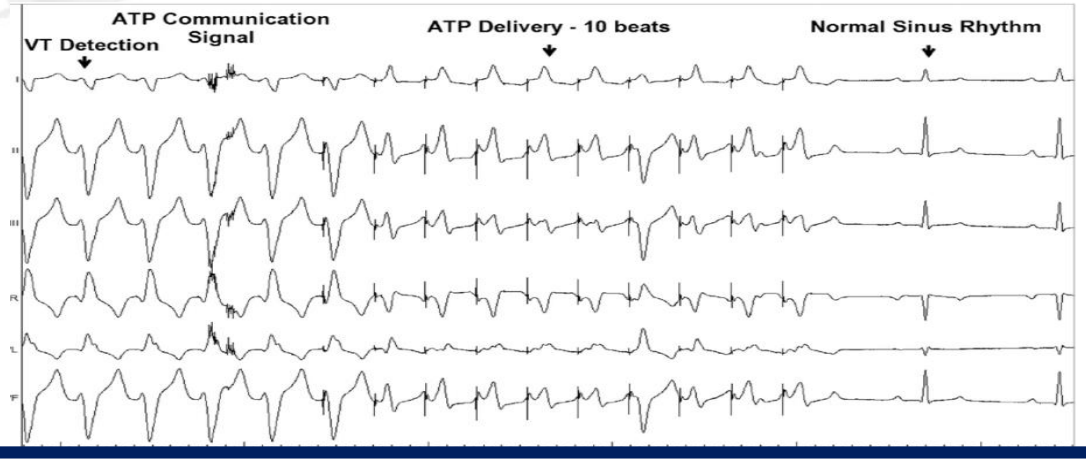
? Smaller generator

? Leadless pacemaker

Communicating Leadless Anti-Tachycardia Pacemaker and S-ICD

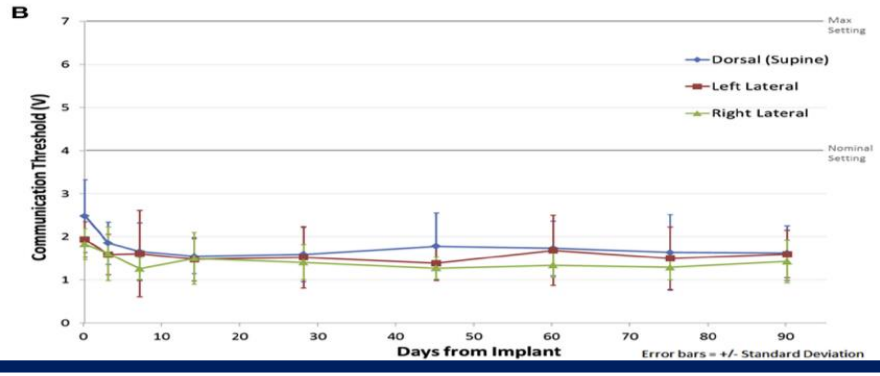






A

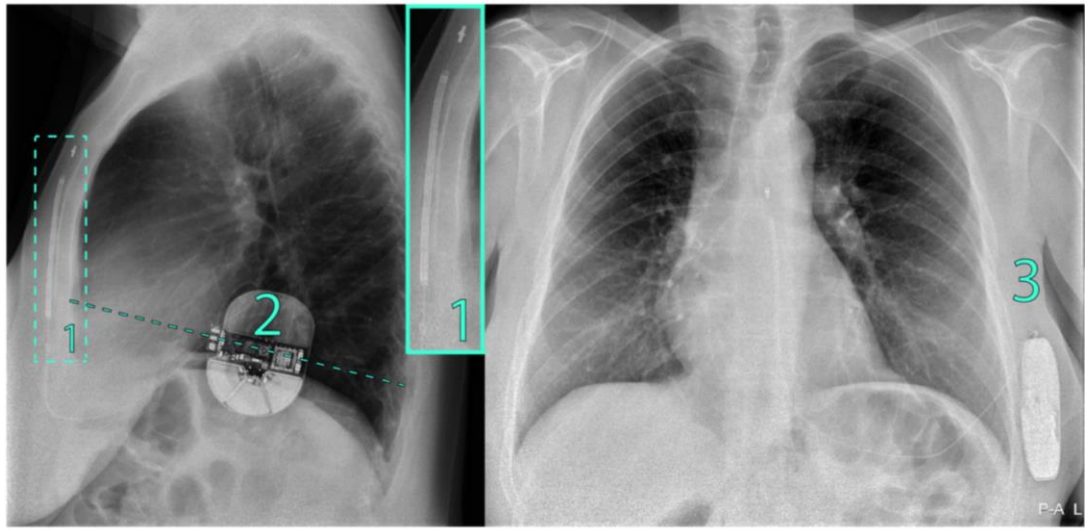
	Acute	Chronic
	n = 39	n = 23
Device-device communication success, n/N (%)	306/309 (99)	92/92 (100)

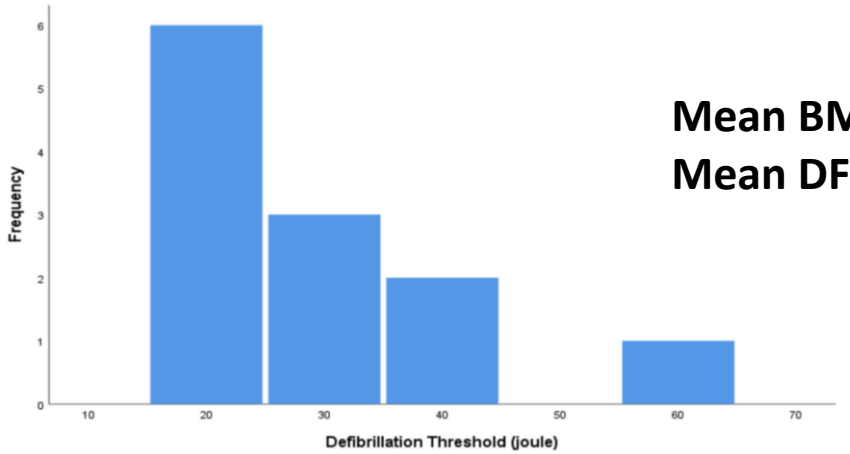


Tjong FV, et al. JACC EP 2017

Low Energy Defibrillation with S-ICD

Outcomes	30 J Single shock conversion test (n = 15)	Step-down DFT protocol (n = 12)
Procedure duration, minutes	34 (±3)	44 (±7)
DFT, Joule	30	29 (±12)
High voltage impedance, Ω[a]	84 (±27)	76 (±18)
High voltage impedance range	53-159	53-114
Patients with DFT 20 J	N/A	6 (50%)
Patients with DFT 30 J	14 (93%)	3 (25%)
Patients with DFT 40 J	N/A	2 (17%)
Patients with DFT 50 J	N/A	0 (0%)
Patients with DFT 60 J	N/A	1 (8%)
Patients with DFT 70 J	N/A	0 (0%)
Time to therapy 20 J, s	N/A	11 (±2)
Time to therapy 30 J, s	12 (±1)	14 (±4)
Time to therapy 40 J, s	N/A	15 (±2)
Time to therapy 50 J, s	N/A	12 (±1)
Time to therapy 60 J, s	N/A	14[b]
Time to therapy 70 J, s	N/A	17[b]
DFT related complications, n	0 (0%)	0 (0%)
Periprocedural complications, n	0 (0%)	0 (0%)



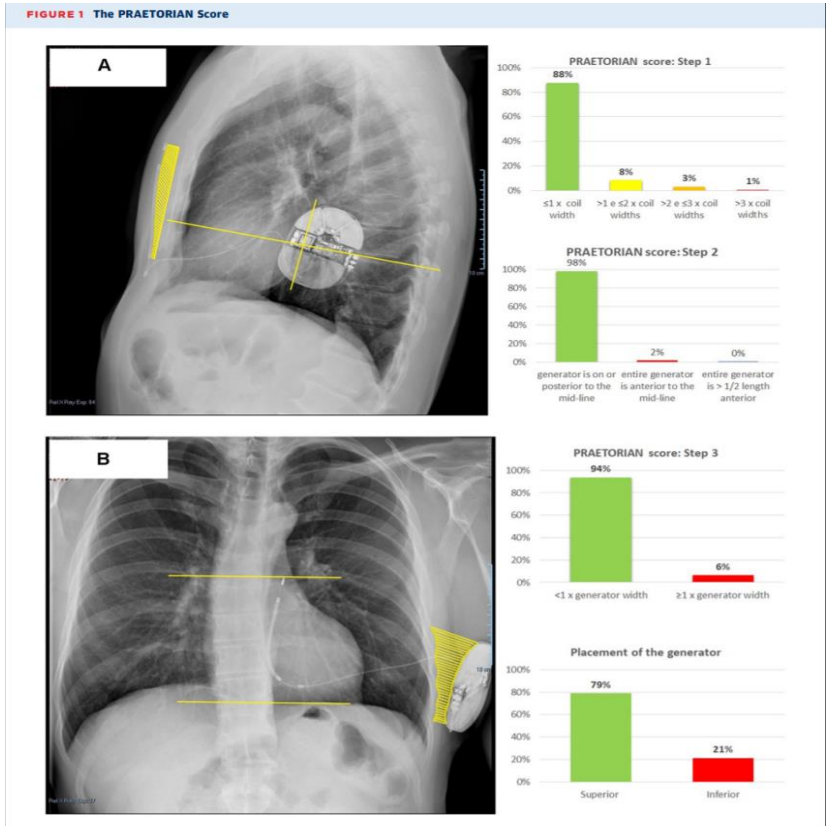


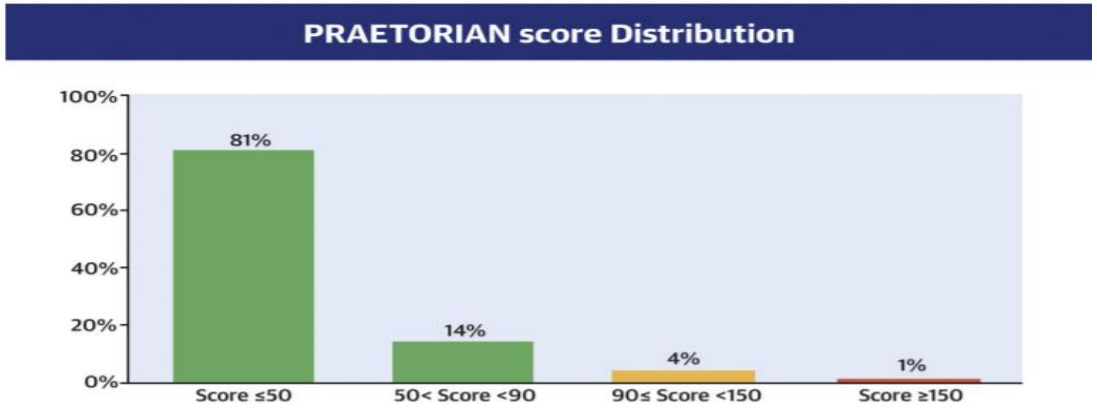
Mean BMI 25
Mean DFT 29J

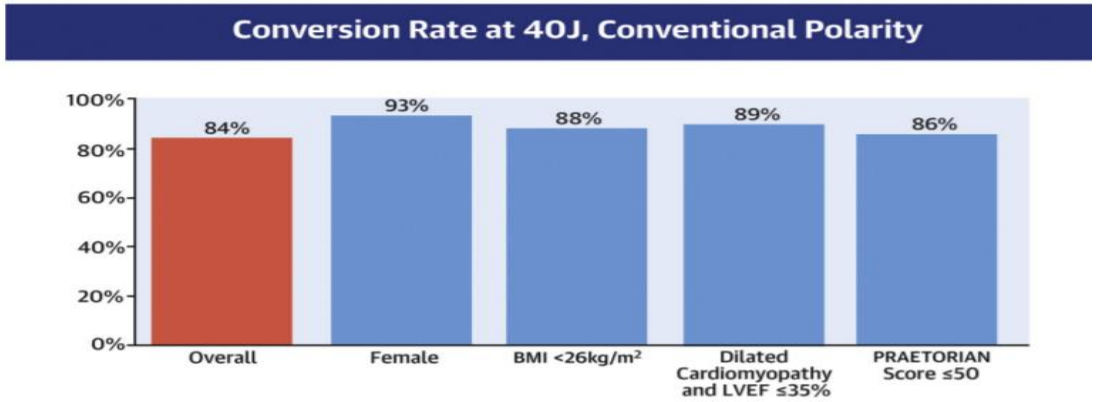
? Smaller Generator

Quast AB, et al. JCE 2019

DFT Testing for S-ICD







- A high rate of defibrillation success with 40-J shocks in S-ICD systems implanted by means of intra-muscular implant techniques.
- The variables associated with shock failure were male gender, higher body mass index, and suboptimal device position according to the PRAETORIAN score.

Biffi M, et al. J Am Coll Cardiol EP 2021

Asian Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) True Defibrillation Threshold (DFT) Study

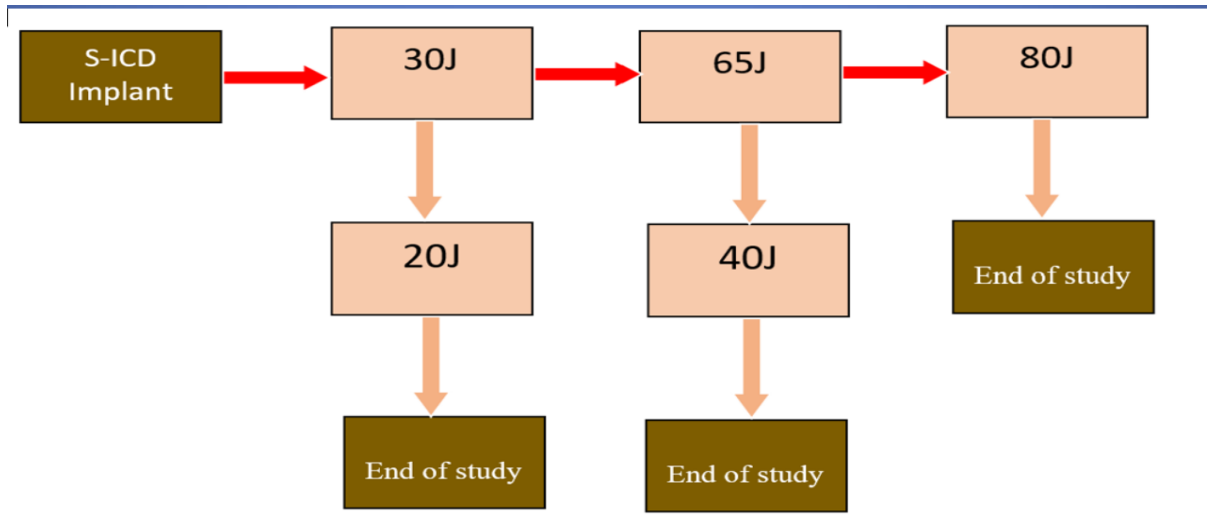
Primary Endpoint

- Investigate the true DFT of S-ICD in Asian population.

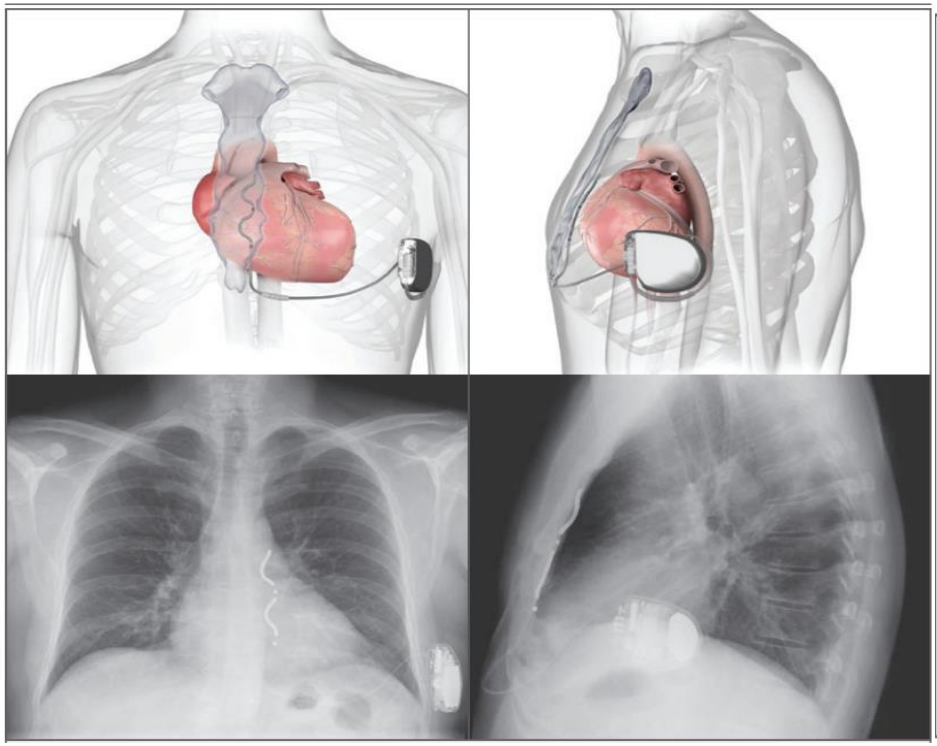
Secondary Endpoints

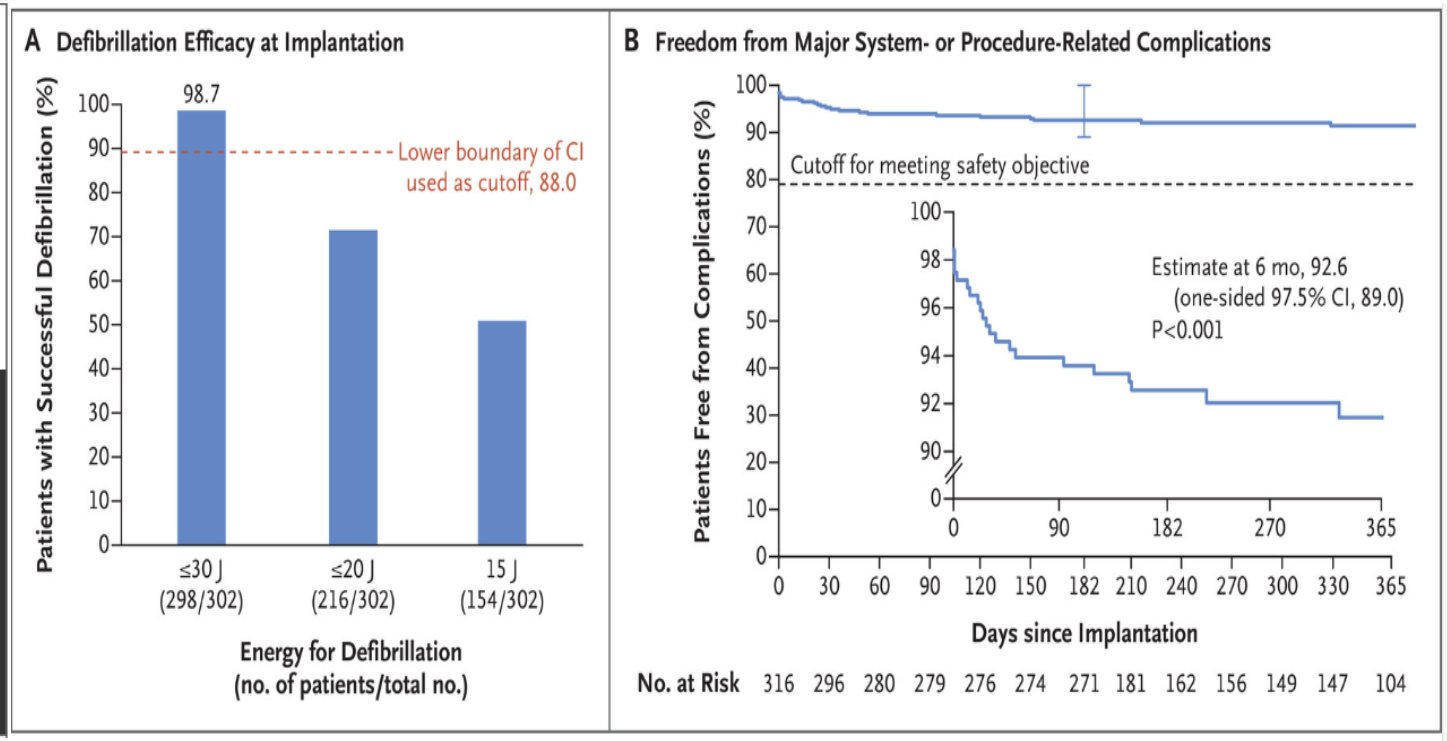
- Safety outcome of this acute feasibility study
- Factors that affect DFT of S-ICD.

Study Design



Extravascular Implantable Cardioverter–Defibrillator





- **Free from major system- or procedure-related complications at 6 months was 92.6%; and No major intraprocedural complications were reported. At 6 months, 25 major complications were observed, in 23 of 316 patients (7.3%).**
- **The success rate of antitachycardia pacing, as assessed with generalized estimating equations, was 50.8% (95% CI, 23.3 to 77.8. 29 patients 99%) with inappropriate shocks and 8 systems (2.5% were explanted without extravascular ICD replacement over the 10.6-month mean follow-up period.**

Friedman B, et al. NEJM 2022

Conclusions

- S-ICD is an established device therapy that can avoid the serious complications related to conventional transvenous ICD
- S-ICD is an alternative ICD option for prevention of SCD in selected population for primary and secondary prevention in pts with SHD
- Improving implant experience, eg different screening and implant method in different pts population
- Emerging techniques should further enhances S-ICD Therapies.

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