PLACE

PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

ROMA
Centro Congressi
di Confindustria
Auditorium
della Tecnica

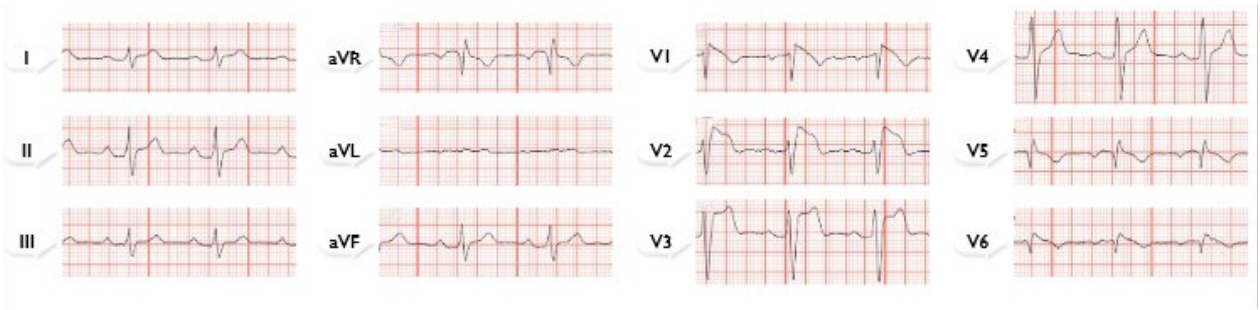
9ª Edizione

30 Settembre
1 Ottobre
2022

Sindrome di Brugada nel 2022

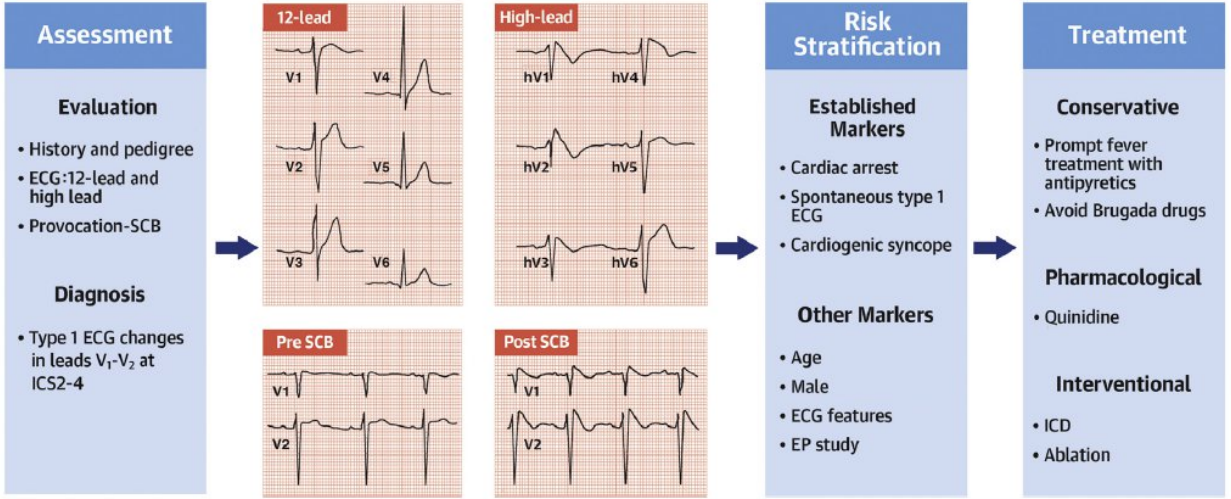
Predittori di shock inappropriato in pazienti con sindrome di Brugada e portatori di defibrillatore sottocutaneo

Casu Gavino, MD, FESC
Cardiologia Clinica e Interventistica
Azienda Ospedaliero Universitaria Sassari



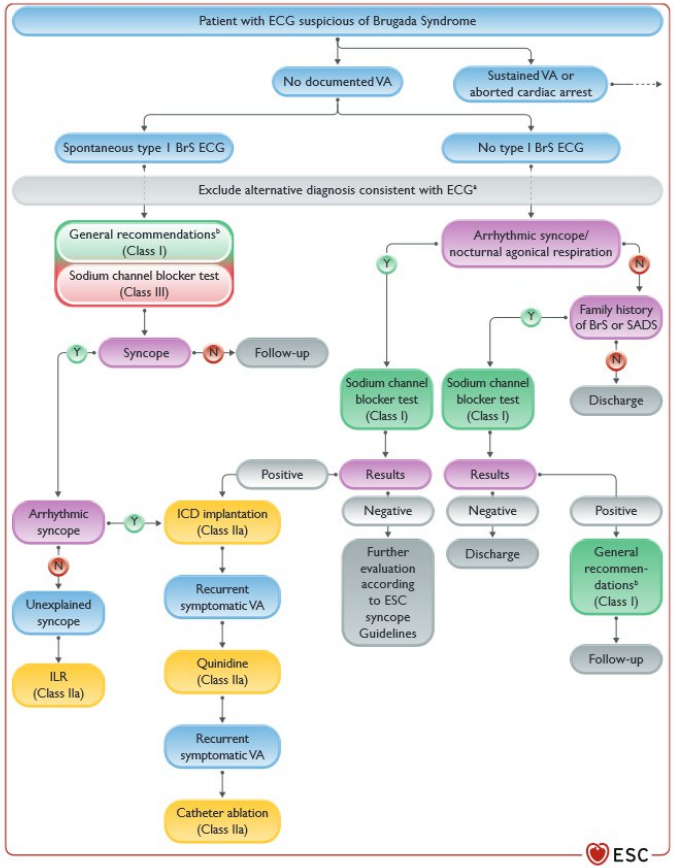
- Prevalence ~ 1:2000
- ~80% Male, 4° decade
- Predisposition to syncope and SCD secondary to polymorphic ventricular arrhythmia, during sleep/fever
- ~20% *SCN5A* mutations, growing evidence of oligogenic/polygenic basis
- Diagnostic ECG=Pattern type 1 in at least 1 right precordial lead
  (spontaneous and/or after ajmaline/flecainide challenge)
- ECG=dynamic
- Growing evidence of epicardial arrhythmic substrate within the ROVT

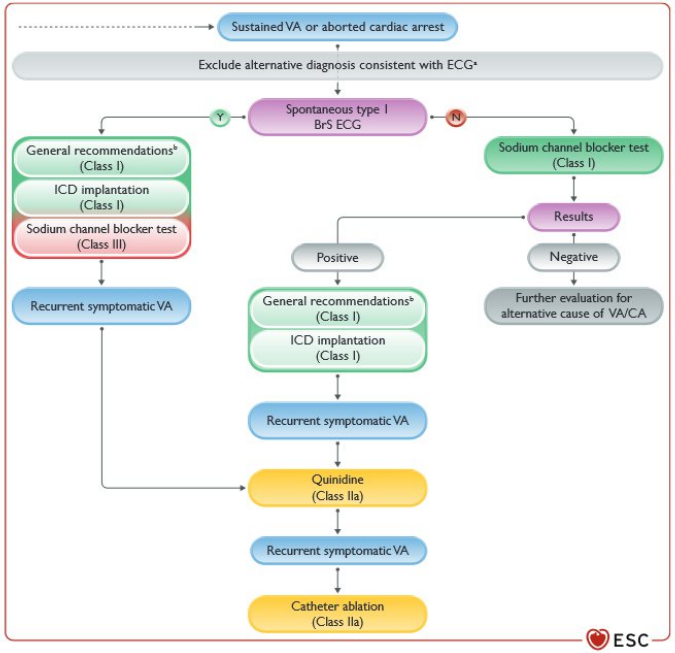
Clinical Approach to Brugada Syndrome



- ALL PATIENTS
- ARRHYTHMIC STORM
- SUPRAVENTRICULAR ARRHYTHMIAS
- REFUSES ICD
- HIGH-RISK

Krahn AD, et al. J Am Coll Cardiol EP. 2022;8(3):386-405.


Patient with ECG suspicious of Brugada Syndrome
No documented VA
Sustained VA or aborted cardiac arrest
Spontaneous type 1 BrS ECG
No type 1 BrS ECG
Exclude alternative diagnosis consistent with ECG[a]
General recommendations[b] (Class I)
Sodium channel blocker test (Class III)
Arrhythmic syncope/ nocturnal agonical respiration
Y
N
Family history of BrS or SADS
Syncope
Follow-up
Discharge
Sodium channel blocker test (Class I)
Sodium channel blocker test (Class I)
Positive
Results
Results
Negative
Negative
Positive
Arrhythmic syncope
ICD implantation (Class IIa)
Further evaluation according to ESC syncope Guidelines
Discharge
General recommen-dations[b] (Class I)
Unexplained syncope
Recurrent symptomatic VA
ILR (Class IIa)
Quinidine (Class IIa)
Follow-up
Recurrent symptomatic VA
Catheter ablation (Class IIa)
ESC

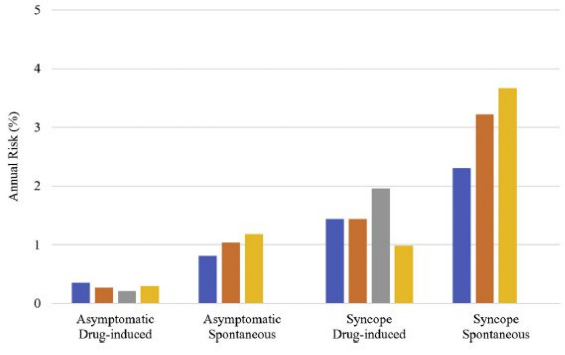

Sustained VA or aborted cardiac arrest
Exclude alternative diagnosis consistent with ECG[a]
Y
Spontaneous type 1 BrS ECG
N
General recommendations[b] (Class I)
ICD implantation (Class I)
Sodium channel blocker test (Class III)
Sodium channel blocker test (Class I)
Results
Positive
Negative
Recurrent symptomatic VA
General recommendations[b] (Class I)
ICD implantation (Class I)
Further evaluation for alternative cause of VA/CA
Recurrent symptomatic VA
Quinidine (Class IIa)
Recurrent symptomatic VA
Catheter ablation (Class IIa)
ESC

ICD IMPLANT INDICATIONS

ICD implantation is recommended in patients with a diagnosis of Brugada syndrome who (a) Are survivors of an aborted cardiac arrest and/or (b) Have documented spontaneous sustained VT.	I	C
ICD implantation should be considered in patients with a spontaneous diagnostic type I ECG pattern and history of syncope.	IIa	C
ICD implantation may be considered in patients with a diagnosis of Brugada syndrome who develop VF during PVS with two or three extrastimuli at two sites.	IIb	C

2015 Priori SG EHJ

FIGURE 5 Risk of Serious Arrhythmic Events Stratified by Clinical Factors



Annual risk of serious arrhythmic events in patients with Brugada syndrome: asymptomatic + drug-induced (0.21%-0.3%), asymptomatic + spontaneous (0.81%-1.18%), syncope + drug-induced (0.98%-1.96%), and syncope + spontaneous (2.3%-3.66%). Developed using data reported by Probst et al[125] **(blue bars)**, Sroubek et al[67] **(orange bars)**, Rattanawong et al[136] **(gray bars)**, and Honarbakhsh et al[131] **(yellow bars)**.

Krahn et al JACC: CLINICAL ELECTROPHYSIOLOGY

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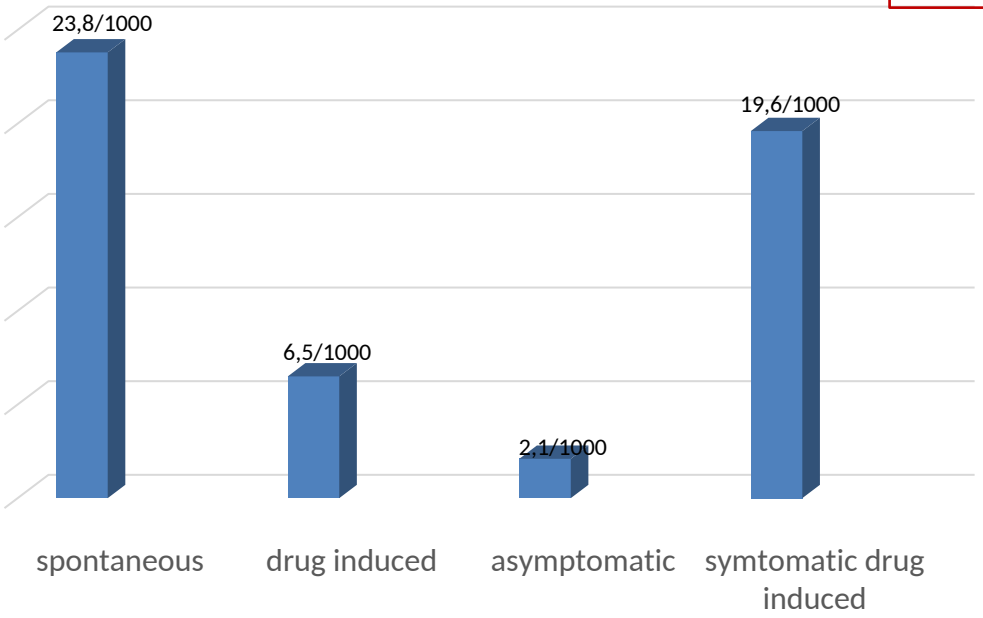
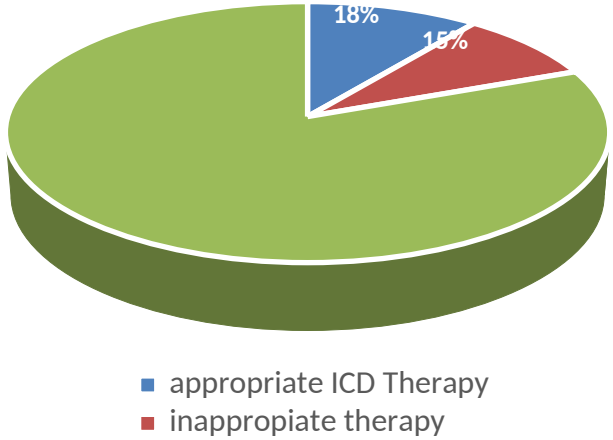
Annual incidence of SAEs in excess of 1,4%
Vs
3,3% annual rate of inappropriate shocks
4,5% annual rate of other complication

Pooled annual incidences of SAEs

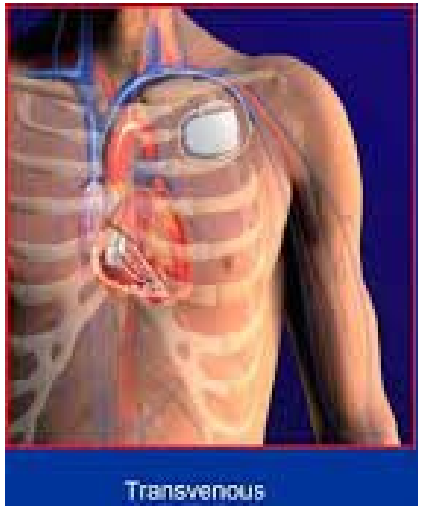




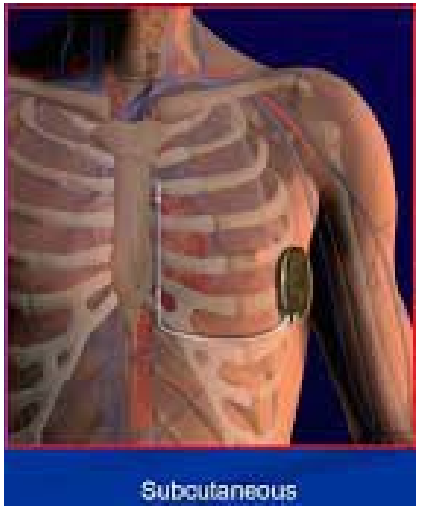
Rattanawong. J Cardiovasc Elettrophysiol , 2020

Dereci a J Am Coll Cardiovasc EP 2019

SCD incidence
0,19% in BrS without ICD Vs 0.10% in BrS with ICD



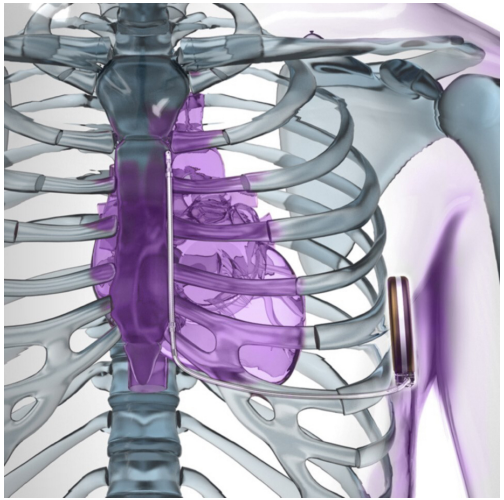
Capability of atrial pacing



Mitigating intravascular infection risk

WHY CHOOSE S-ICD?

- Transvenous ICDs (TV-ICD) are effective, but come with limitations
  - 10-20% lead failure after 6 years of follow-up[1]
- Subcutaneous ICDs (S-ICD) are designed to overcome these lead-related complications
  - Young patients with preserved LVEF [2-4]
  - A high shock efficacy compared to TV-ICD[2-4]
  - Less ICD related complications [5]
  - More inappropriate shocks [5,6]



1. Koneru JAHA 2018
2. Boersma JACC 2017
3. Weiss Circ 2013
4. Boersma Heart Rhythm 2019
5. Bassu-Ray JACC EP 2017
6. Moss NEJM 2012

WHY CHOOSE S-ICD IN BRUGADA SYNDROME?

- Younger patients
- Active (no physical restrictions)
- Long-life with the ICD=Higher risk of lead-related complications
- Less invasive

Sonny Colbrelli

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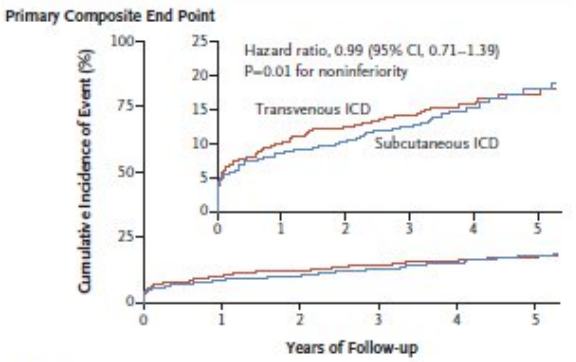
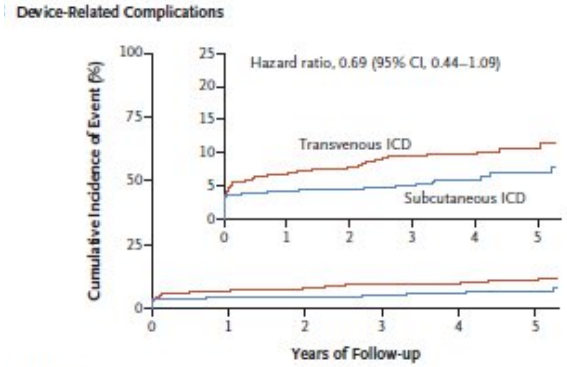
Subcutaneous or Transvenous Defibrillator Therapy

«PRAETORIAN study»





- PRIMARY END-POINT: DEVICE-RELATED COMPLICATIONS + INAPPROPRIATE SHOCKS
- SECONDARY END-POINTS: DEATH, APPROPRIATE SHOCKS
- S-ICD NON INFERIOR TO TV-ICD RESPECT TO DEVICE-RELATED COMPLICATIONS + INAPPROPRIATE SHOCKS
- HIGHER CUMULATIVE INCIDENCE OF DEVICE-RELATED COMPLICATIONS IN TV-ICD AND OF INAPPROPRIATE SHOCKS IN S-ICD (BUT STUDY WAS NOT POWERED FOR THESE COMPARISONS)
- 78% S-ICD SMART-PASS WAS NOT AVAILABLE OR ACTIVATED

2020 Knops RE NEJM

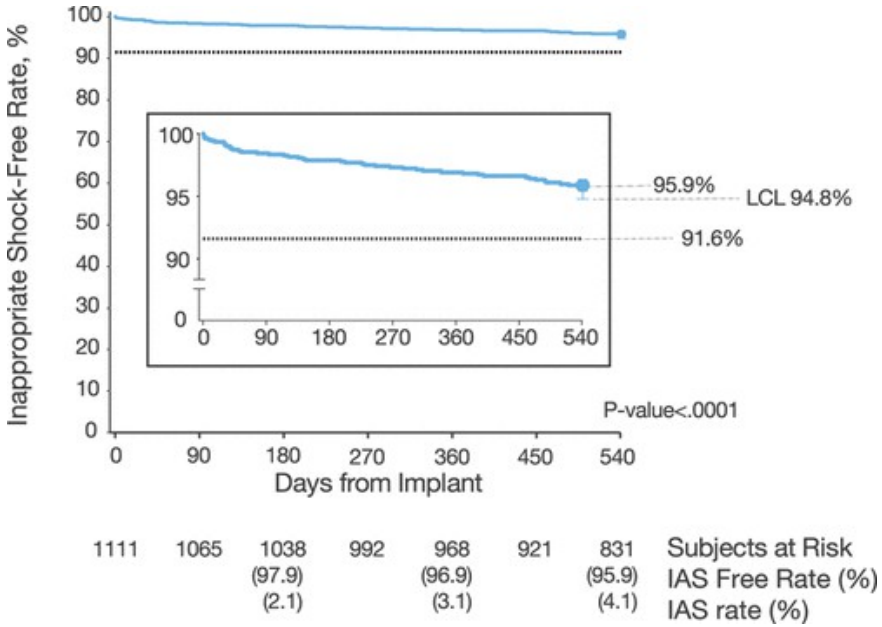
«PRAETORIAN study»

Table 2. Primary Composite End Point.*

End point	Subcutaneous ICD (N=426)	Transvenous ICD (N=423)	Hazard Ratio (95% CI)
Primary composite end point — no. (%)	68 (15.1)	68 (15.7)	0.99 (0.71–1.39)†
Components of primary end point			
Device-related complication — no. (%)	31 (5.9)	44 (9.8)	0.69 (0.44–1.09)
Infection — no.‡	4	8	
Bleeding — no.	8	2	
Thrombotic event — no.	1	2	
Pneumothorax — no.§	0	4	
Lead perforation — no.§	0	4	
Tamponade — no.	0	2	
Lead repositioning — no.§	2	7	
Other lead or device complication — no.	19	20	
Lead replacement§¶	3	9	
Device malfunction	4	6	
Sensing issues	4	0	
Pacing indication‖	5	1	
Implantation failure	0	3	
Defibrillation test failure**	3	0	
Pain or discomfort	2	3	
Inappropriate shock — no. (%)††	41 (9.7)	29 (7.3)	1.43 (0.89–2.30)
Atrial fibrillation or supraventricular tachycardia — no.	11	27	
Cardiac oversensing — no.‡‡	24	2	
Noncardiac oversensing — no.§§	8	0	

- S-ICD:
  - FEWER LEAD-RELATED COMPLICATIONS FEWER
  - FEWER SUBSEQUENT SURGICAL REINTERVENTIONS
- BUT:
  - MORE POCKET HEMATOMAS
- FUTURE INTERESTING DATA:
  - LONG-TERM LEAD COMPLICATIONS
  - BATTERY LONGEVITY

Primary Results From the Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) Trial

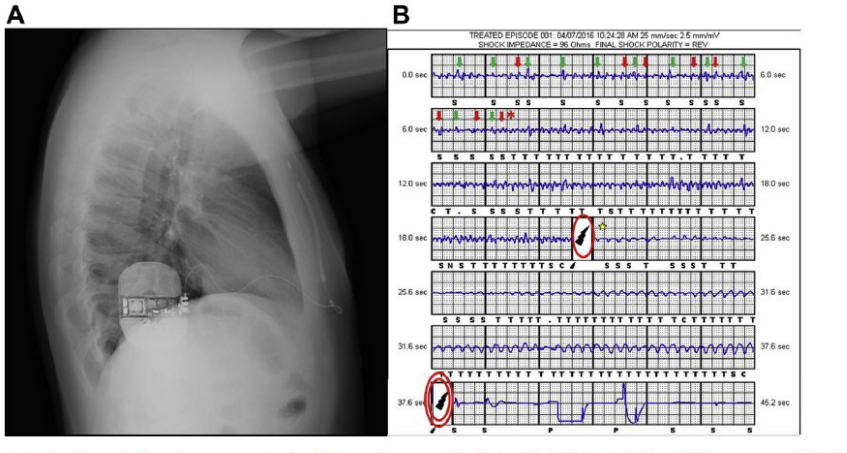


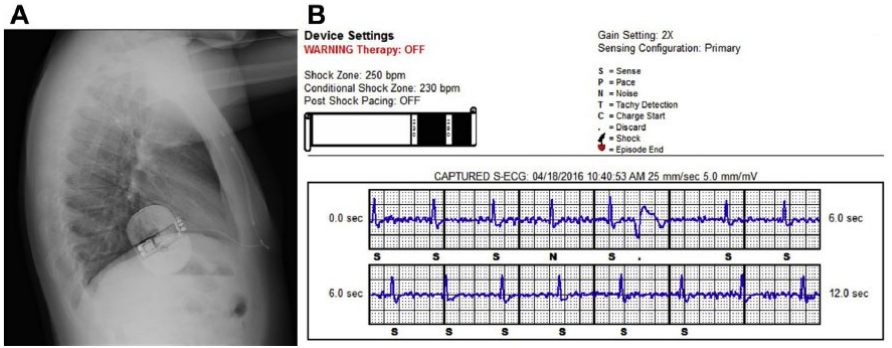
Michael R. Gold. Circulation. , Volume: 143, Issue: 1, Pages: 7-17, DOI: (10.1161/CIRCULATIONAHA.120.048728)

S-ICD PROBLEMS

- NOT EVERY PATIENT IS A GOOD CANDIDATE (SCREENING TEST)
- HIGHER RISK OF INAPPROPRIATE SHOCKS (OVERSENSING BEING THE MAIN CAUSE, PARTICULARLY TWOS)
- SHOCKS CAUSED BY CARDIAC/NON-CARDIAC OVERSENSING ARE LESS MODIFIABLE BY DEVICE PROGRAMMING

Changing place, changing future: Repositioning a subcutaneous implantable cardioverter-defibrillator can resolve inappropriate shocks secondary to myopotential oversensing





Berne P, Casu G.Heart Rhythm Case Rep. 2017 Aug

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EFFORTLESS
CHANNELOPATHIES vs OTHERS

KEY FINDINGS

- In the EFFORTLESS Registry, channelopathy patients had equivalent appropriate shock and complication rates to non-channelopathy patients.
- There was a lower burden of appropriate shocks for monomorphic ventricular tachycardia (VT) in channelopathy patients but equivalent polymorphic VT shock rate.
- Annualized appropriate shock, inappropriate shock, and complication rates appear to be lower for the subcutaneous vs meta-analysis transvenous implantable cardioverter-defibrillator patients, particularly lead complications.

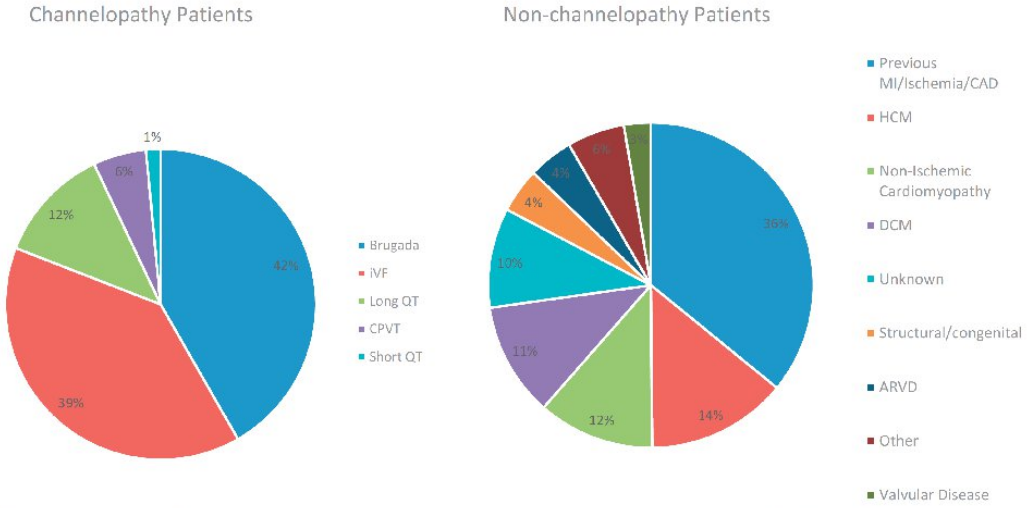

Figure 1 Diagnoses in the EFFORTLESS channelopathy and non-channelopathy cohorts. ARVD = arrhythmogenic right ventricular dysplasia; CAD = coronary artery disease; CPVT = catecholaminergic polymorphic ventricular tachycardia; DCM = dilated cardiomyopathy; HCM = hypertrophic cardiomyopathy; iVF = idiopathic ventricular fibrillation; MI = myocardial infarction.

CHANNELOPATHY PATIENTS:

- YOUNGER (39 vs 52 years, p<0.001)
- LESS LIKELY TO RECEIVE A PRIMARY PREVENTION S-ICD (57.8 vs 66.7%, p<0.02)

2020 Lambiase PD Heart Rhythm

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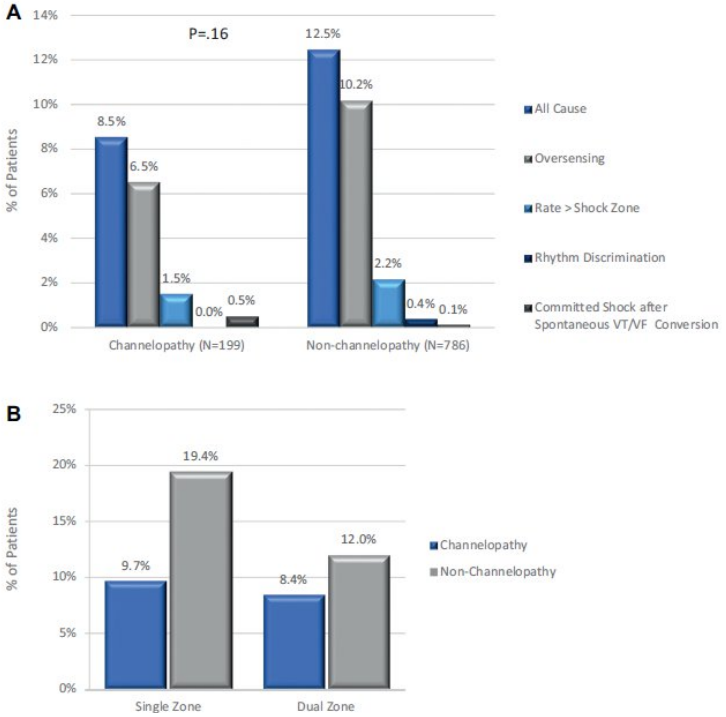
EFFORTLESS
Inappropiate Shocks

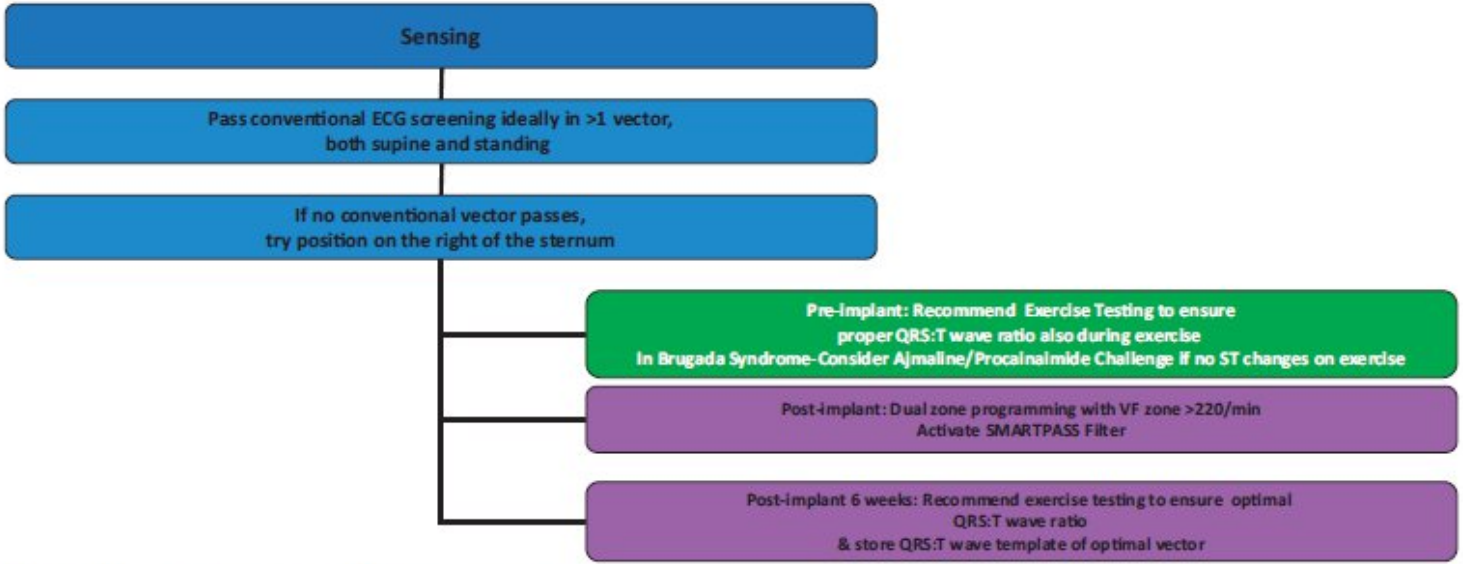


INCIDENCE DID NOT DIFFER

CAUSES ARE DIFFERENT:

- CHAN: OVERSENSING (INCLUDING TWOS)
- NON-CHAN: SUPRAVENTRICULAR TACHY

Proposed strategy to avoid inappropriate shocks in channelopathy patients. Ideally, .1 vector should be identified to allow more programming options if T-wave oversensing occurs.

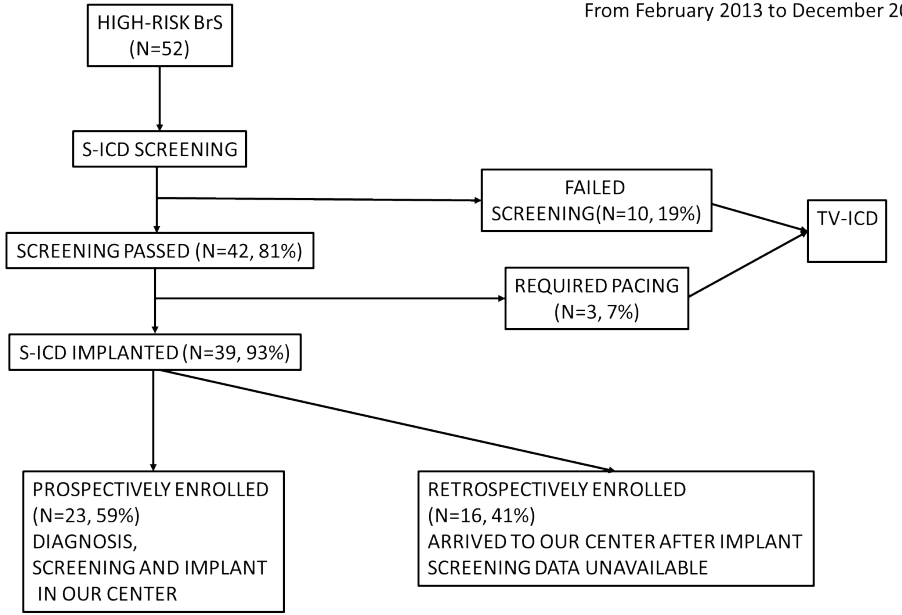


2020 Lambiase PD Heart Rhythm

Inappropiate shocks and Brugada Syndrome

- ADULT PATIENTS
- DIAGNOSIS OF BRUGADA SYNDROME
- HIGH ARRHYTHMIC RISK
  - ABORTED SUDDEN CARDIAC ARREST
  - ARRHTHMIC SYNCOPE
  - SUSTAINED VENTRICULAR ARRHYTHMIA INDUCIBLE DURING EPS
- IMPLANTED WITH S-ICD

From February 2013 to December 2019

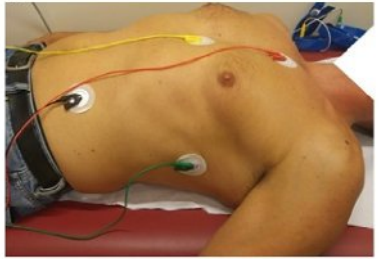


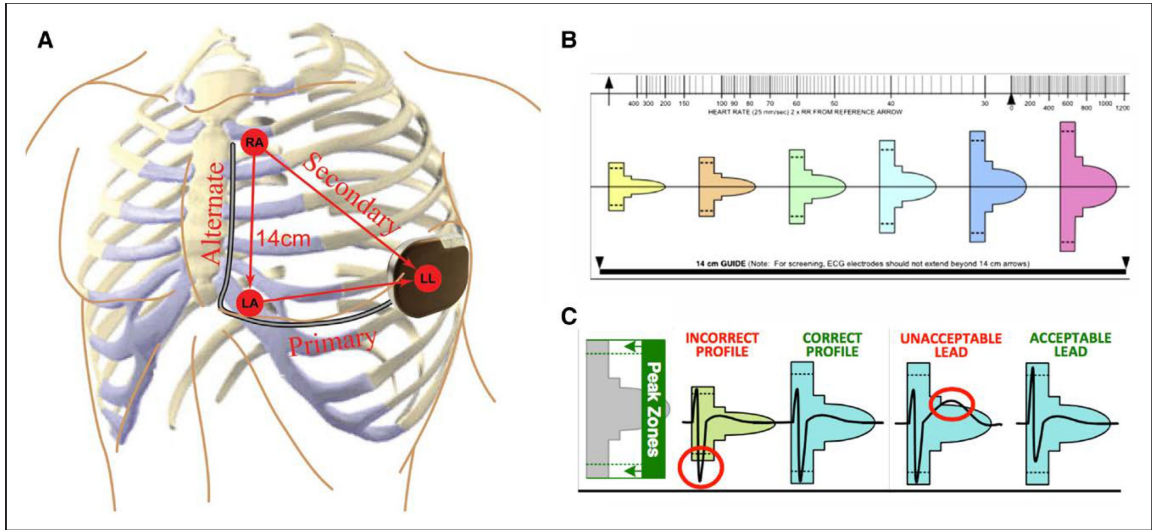
Casu G. J Electrophysiol 2021

BASELINE CHARACTERISTICS

	n = 39
Male, *n* (%)	27 (69%)
Age at diagnosis (years)	46 ± 13
Age at S-ICD implant (years)	48 ± 13
LVEF (%)	64 ± 5
Weight (kg)	73 ± 12
Height (m)	1.7 ± 0.07
BMI	25.7 ± 3.5
Proband, *n* (%)	31 (79%)
Family history of SCD, *n* (%)	20 (51%)
Supraventricular tachycardia and/or atrial fibrillation before diagnosis	0
Primary prevention of SCD (indication of implant), *n* (%)	37 (95%)
Indication of implant, *n* (%)	
Aborted SCD	2 (5%)
Arrhythmic syncope	29 (74%)
Positive EPS	8 (21%)
ECG at diagnosis	
Rhythm	SR
Heart rate (b.p.m.)	71 ± 11
PR interval (ms)	160 ± 24
QRS (ms)	97.6 ± 17
QTc interval (ms)	397 ± 24.8
Mean J point elevation (V2) at diagnosis (mm)	3 ± 1
Spontaneous type 1 pattern at diagnosis, *n* (%)	12 (31%)
Spontaneous type 1 pattern anytime (at diagnosis or during follow-up), *n* (%)	13 (33%)
Automated screening test, *n* (%)	24 (62%)

MANUAL S-ICD SCREENING (15, 38%)





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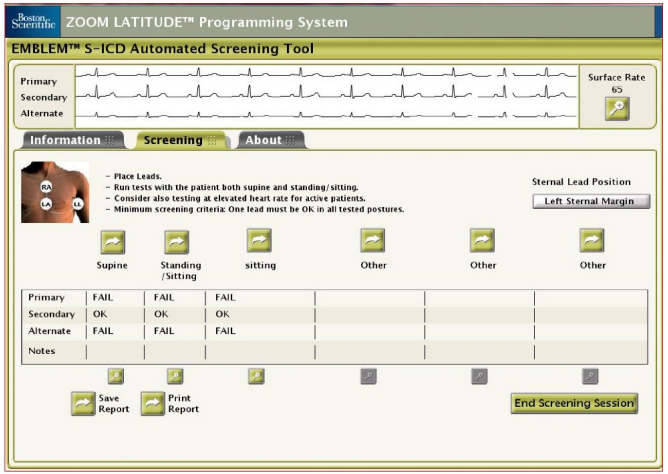
AUTOMATED S-ICD SCREENING (24, 62%)

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AUTOMATED SCREENING TOOL (AST)

Noise=T-wave
Defibrillator Automated Screening Score (DASS)=QRS/T relationship
Electrode pass true if DASS is ≥ 100
At least one electrode pass required for implant

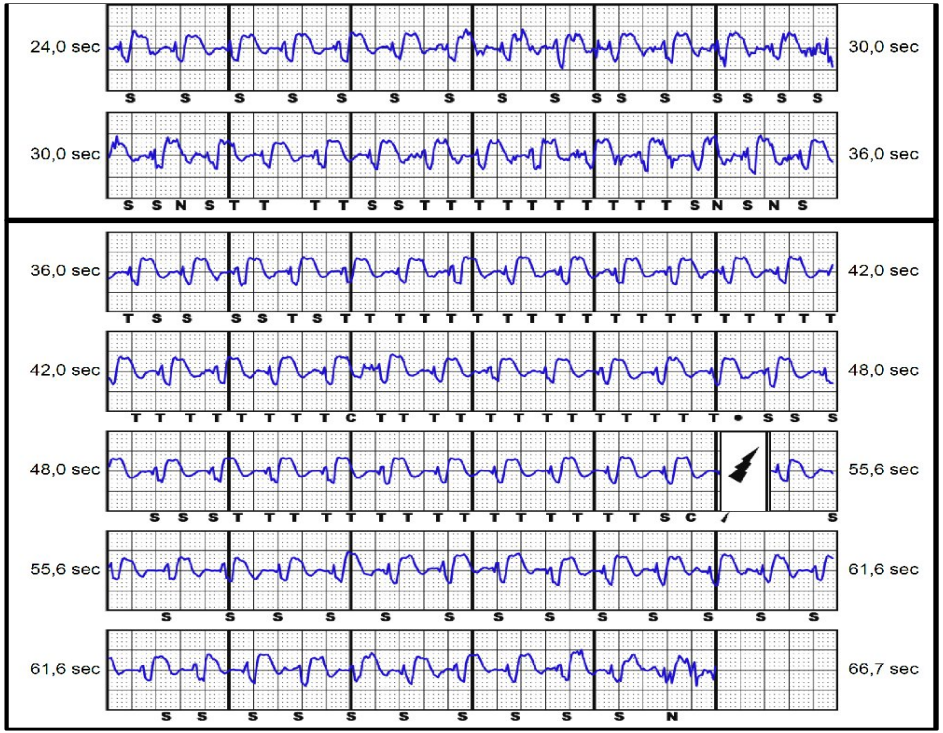
- Mean follow-up: 26±21 months
- No appropriate shock (AS)
- 7 patients inappropriate shocks (IS)
- Mean time implantation-IS: 9±8 months
- Cause of the IS:
  - Oversensing (4, 57%)
  - Electric noise by trapped air escaping from the device header (2, 29%)
  - Paroxysmal SVT (1, 14%)

TABLE 2 Patients with inappropriate shocks, causes, number of shocks/patient, their causes, SMART Pass filter and sensing vector programmed

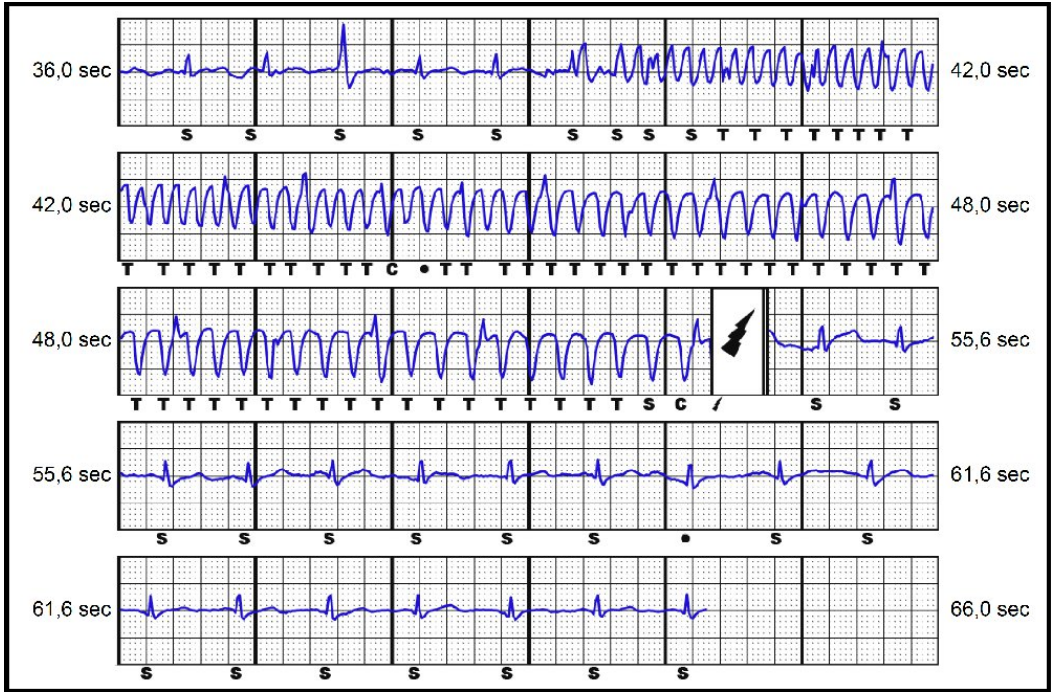
Patient ID	Cause of IS	No. of IS	HR during IS episode (bpm)	Activity during IS episode	Management	SMART Pass programming	Vector programming at implant and IS
#1	TWOS	32	90–145	Exercise, leaning forward, rest	TV-ICD recommended, patients refused	Not available	Primary
#2	TWOS	4	140	Riding a bicycle	Reprograming vector and gain (during exercise test) + bisoprolol	On	Primary
			145	Riding a bicycle			
			145	Moving heavy gas cylinders at work			
			135	Sawing wood			
#3	TWOS (exercise)	2	145	Working in the field	Reprogramming vector and gain	Changes to off	Primary
			130	Moving heavy gas cylinders at work			
#4	TWOS (exercise)	1	90	Doing crunches	Reprogramming vector and gain	Not available	Primary
#5	Noise secondary to air escape from the device header	1	80	Getting out of bed	No program modifications	On	Secondary
#6	Noise secondary to air escape from the device header	1	90	Walking	No program modifications	On	Secondary
#7	Paroxysmal supraventricular tachycardia	1	240	At rest	RFA suggested, patient refused	Changes to off	Secondary

Abbreviations: HR, heart rate; IS, inappropriate shock; RFA, radiofrequency ablation; TV-ICD, transvenous implantable cardioverter-defibrillator; TWOS, T-wave oversensing.

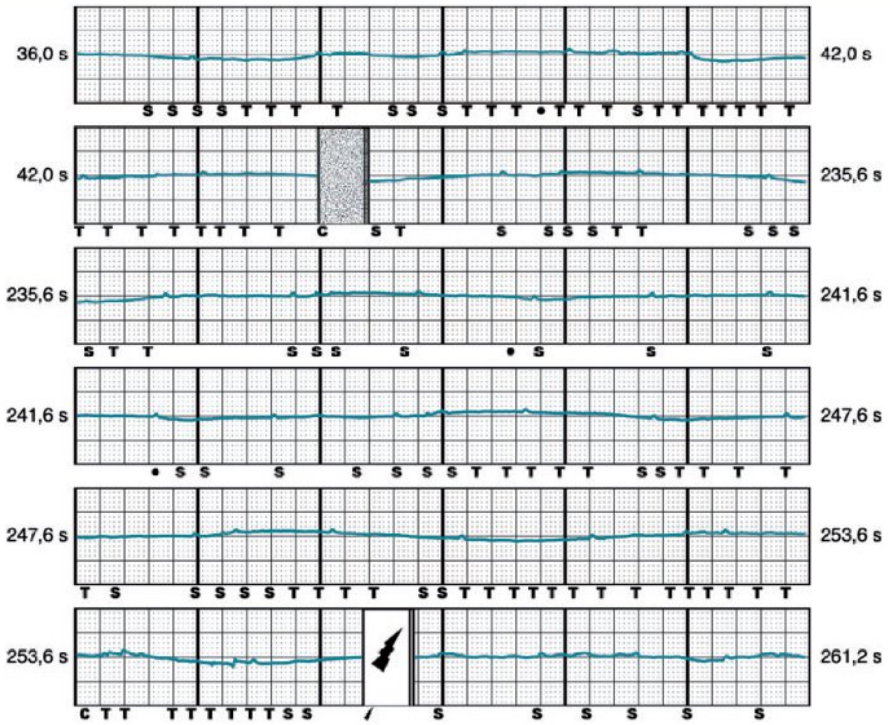
IS SECONDARY TO TWOS



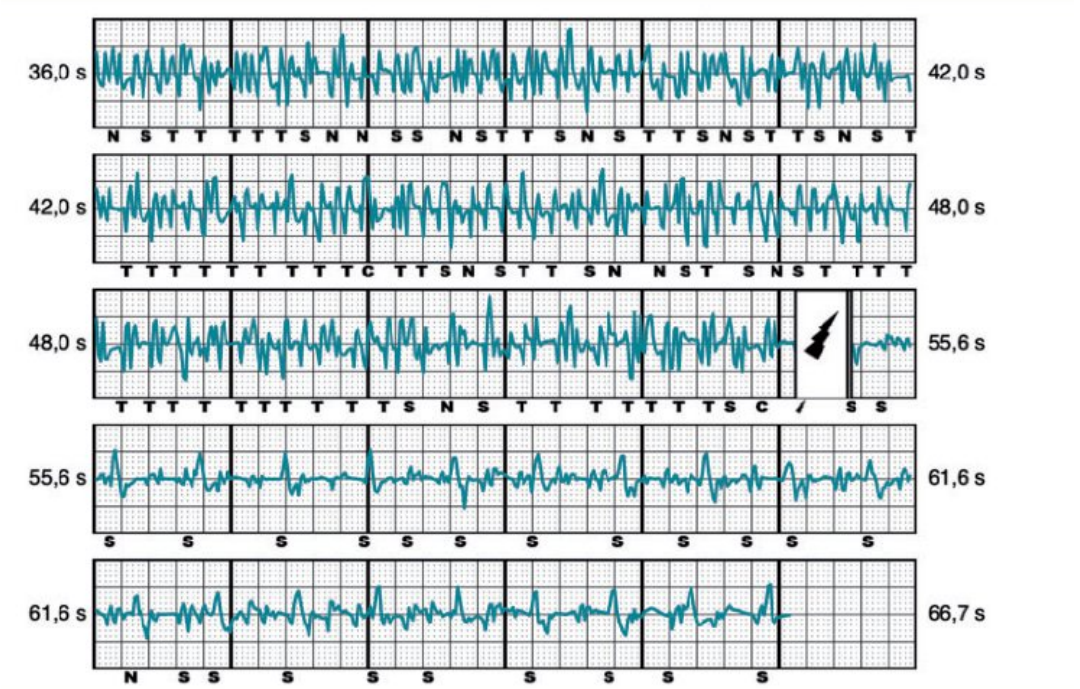
IS AIR ESCAPE FROM THE DEVICE HEADER



IS SECONDARY TO UNDERSENSING



IS SECONDARY TO MYOPOTENTIALS



BASELINE CHARACTERISTICS no IS vs IS

	No IS, *n* (%)	IS, *n* (%)	*p* Value
n (%)	32 (82)	7 (18)	
Male, *n* (%)	21 (66)	6 (86)	NS
Age at diagnosis (years)	48 ± 13	36 ± 8	.018
Age at S-ICD implant (years)	50 ± 23	38 ± 9	.019
LVEF (%)	64 ± 5	64 ± 6	NS
Weight (kg)	73 ± 13	73 ± 9	NS
Height (m)	1.7 ± 0.07	1.66 ± 0.1	NS
BMI	25.6 ± 3.7	26.6 ± 2.5	NS
Proband, *n* (%)	27 (84)	4 (57)	NS
Family history of SCD, *n* (%)	19 (59)	1 (14)	.04
Supraventricular tachycardia and/or atrial fibrillation before diagnosis	0	0	NS
Primary prevention of SCD (Indication of implant), *n* (%)	30 (94%)	7 (100)	NS
ECG at diagnosis			
Rhythm	SR	SR	
Heart rate (b.p.m.)	70 ± 12	75 ± 9	NS
PR interval (ms)	157 ± 21	168 ± 34	NS
QRS (ms)	93.8 ± 12	109 ± 24	NS
QTc interval (ms)	395 ± 24	401 ± 27	NS
Mean J point elevation (V2) at diagnosis (mm)	2.8 ± 0.9	3.1 ± 1.2	NS
Spontaneous type 1 pattern at diagnosis, *n* (%)	8 (25)	4 (57)	NS
Spontaneous type 1 pattern anytime (at diagnosis or during follow-up) *n* (%)	8 (25)	5 (71)	.018
Automated screening test	20 (63)	4 (57)	NS

AUTOMATED SCREEN DATA & DEVICE PROGRAMMING

	IS	No IS	p
QRS voltage, primary vector, supine (mV)	0.58±0.26	1.1±0.35	0.011
DASS, primary vector, supine	123±165	554±390	0.005
DASS, primary vector, standing	162±179	486±388	0.038
SMART Pass AVAILABLE	5/7 (71%)	25/32 (78%)	NS
SMART Pass ON	3/5 (60%)	18/25 (72%)	NS

TABLE 4 Uni- and multivariate Cox regression models for prediction of IS by S-ICD

	Univariate HR (95% CI)	*p* Value	Multivariate HR I (95% CI)	*p* Value	Multivariate HR II (95% CI)	*p* Value
Age at diagnosis	0.93 (0.87–0.99)	.024	0.87 (0.76–0.99)	.037		
Age at S-ICD implant	0.93 (0.88–0.99)	.028			0.89 (0.79–1.00)	.053
Spontaneous type 1 Brugada ECG pattern at diagnosis and/or during follow up	0.20 (0.03–1.03)	.056	0.39 (0.01–14.42)	.611	0.40 (0.005–31.86)	.683
QRS voltage, primary vector supine position	0.03 (0.00–1.34)	.072	0.39 (0–158)	.763	0.27 (0–171)	.693

Abbreviation: BrS, Brugada syndrome; CI, confidence interval; ECG, electrocardiogram; HR, hazard ratio; IS, inappropriate shock; S-ICD, subcutaneous implantable cardioverter-defibrillator.

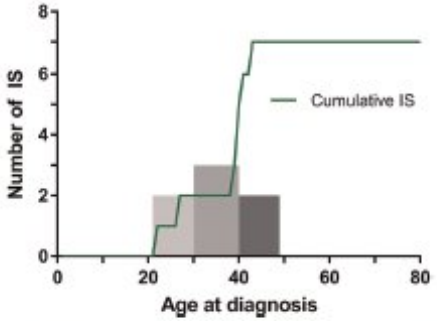
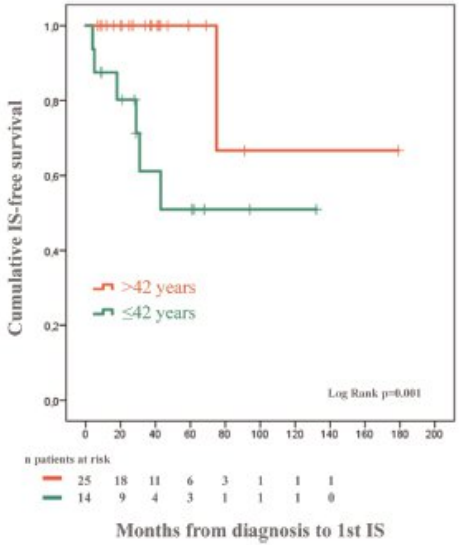


FIGURE 1 Number of IS according to age at diagnosis. Most of the events occur in patients younger than 40 years at diagnosis. IS, nappropriate shock



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ATLAS S-ICD

Avoid Transvenous Leads in Appropriate Subjects S-ICD

Inclusion Criteria

ATLAS S-ICD
Avoid Transvenous Leads in Appropriate Subjects S-ICD

Patient must satisfy any ONE of the following two criteria:

1. Patient is ≥ 18 - 60 years old AND has a standard indication for ICD;

OR

2. Patient is ≥ 18 years old AND has any one of the following present:

- An inherited arrhythmia syndrome (i.e. Long QT, Brugada, ARVC, hypertrophic or dilated cardiomyopathy, early repolarization syndrome, etc.)
- Prior pacemaker or ICD removal for infection
- Need for hemodialysis
- Prior heart valve surgery (repair or replacement)
- Chronic obstructive pulmonary disease (with FEV1 < 1.5 L)

Inappropriate Shocks

	S-ICD	TV-ICD	OR (CI)
N	251	252	
Any inappropriate shock – n (%)	**16 (6.4)**	**7 (2.8)**	**2.38 (0.96- 5.90)**
T-wave oversensing – n (%)	6	0	
Atrial arrhythmia – n (%)	2	5	
Electromagnetic Interference – n (%)*	5	2	
Myopotentials **	3	0	
Any inappropriate shock – rate/yr.	2.7% per yr.	1.2% per yr.	HR = 2.37 (0.98- 5.77)

*** 4 cases in S-ICD and 2 cases in TV-ICD arm due to T.E.N.S., one case each in S-ICD due to LVAD**
**** No lead fractures due to advisory**

Inappropiate shocks and Brugada Syndrome

- IS frequent complication (18% mean follow-up 26±21 months)
- Patients with IS were:
  - Younger at diagnosis
  - Younger at implantation
  - More frequently spontaneous type-1 ECG
  - More frequently family history of SCD
  - Lower QRS voltage in the primary vector during AST
  - Lower DASS in the primary vectorduring AST
- Younger age at diagnosis was independently associated to IS
- **A more thorough screening process and device settings may help prevent IS in this population**:
  - More than 1 vector passed
  - Higher values of DASS and QRS voltage required to pass
  - Screening during type-1 ECG (spontaneous/at the end of ajmaline test)
  - Screening during exercise test
  - Drugs with negative cronotropic effect/avoid certain activities

ESC European Society of Cardiology

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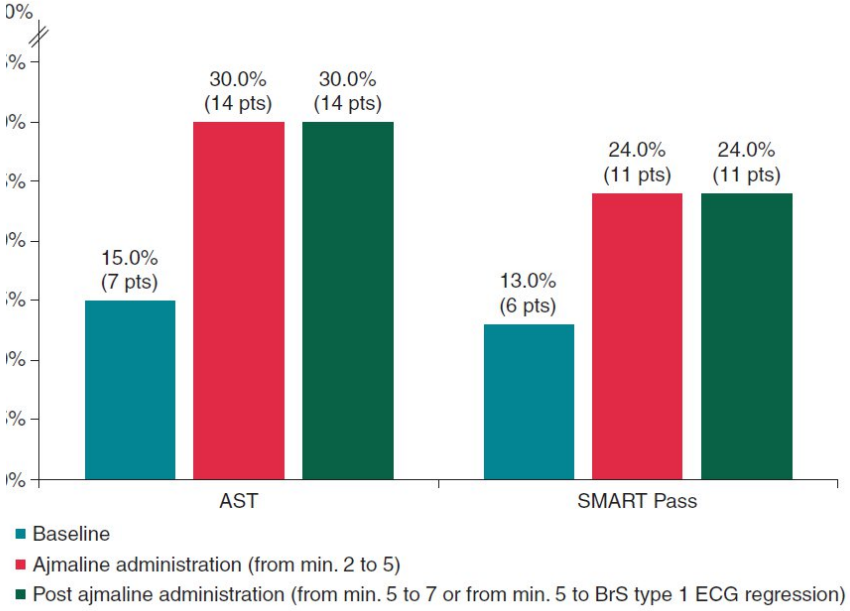
CLINICAL RESEARCH
Channelopathies

Impact of SMART Pass filter in patients with ajmaline-induced Brugada syndrome and subcutaneous implantable cardioverter-defibrillator eligibility failure: results from a prospective multicentre study

Giulio Conte [1,2,3]*, Fabio Cattaneo [1], Carlo de Asmundis [4], Paola Berne [5], Alessandro Vicentini [6], Mehdi Namdar [7], Antonio Scalone [8], Catherine Klersy [9], Maria Luce Caputo [1], Andrea Demarchi [1], Tardu Özkartal [1], Francesca Salghetti [4], Gavino Casu [5], Ilaria Passarelli [6], Stefano Mameli [8], Dipen Shah [7], Haran Burri [7], Gaetano De Ferrari [6], Pedro Brugada [4], and Angelo Auricchio [1,2,3]

What's new?

- One of the five patients with Brugada electrocardiograms (ECGs) fails subcutaneous implantable cardioverter-defibrillator (S-ICD) screening when performed on Brugada type 1 ECG morphologies evoked by ajmaline challenge.
- Up to 40% of sensing vectors are not acceptable in the presence of dynamic Brugada ECG changes, due to low amplitude of the QRS complex or low QRS/T-wave ratio.
- The SMART Pass filter does not significantly reduce the proportion of subjects with an ajmaline-induced Brugada ECG and of vectors ineligible for S-ICD.
- The position of parasternal subcutaneous lead does not influence the screen-out rate of patients with Brugada ECGs or affects the number of acceptable sensing vectors.



Subcutaneous implantable cardioverter-defibrillator screening failure rates before and after ajmaline challenge in patients with BrS (N= 46). BrS, Brugada syndrome

Thank you!