Le défibrillateur sous-cutané

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IMCVO Hôpital privé de Parly 2
20èmes RENCONTRES MÉDICO-CHIRURGICALES
SAMEDI 4 DÉCEMBRE 2021
Palais des Congrès de VERSAILLES
IMCVO Institut des Maladies Cardio-Vasculaires de l'Ouest
Journée Yves Guérin

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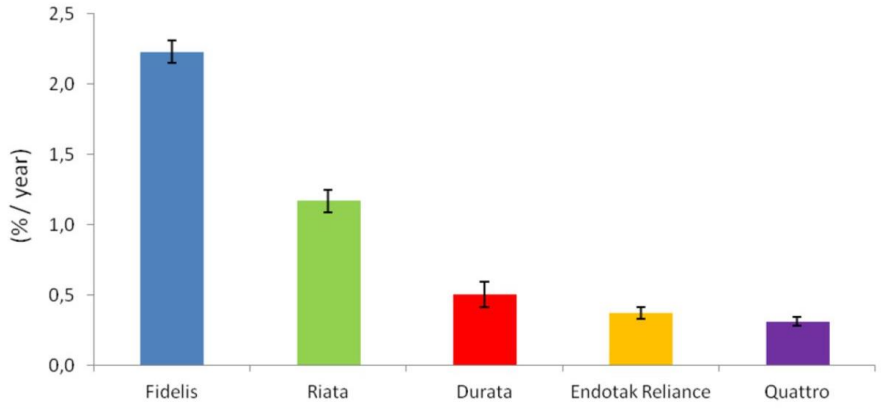
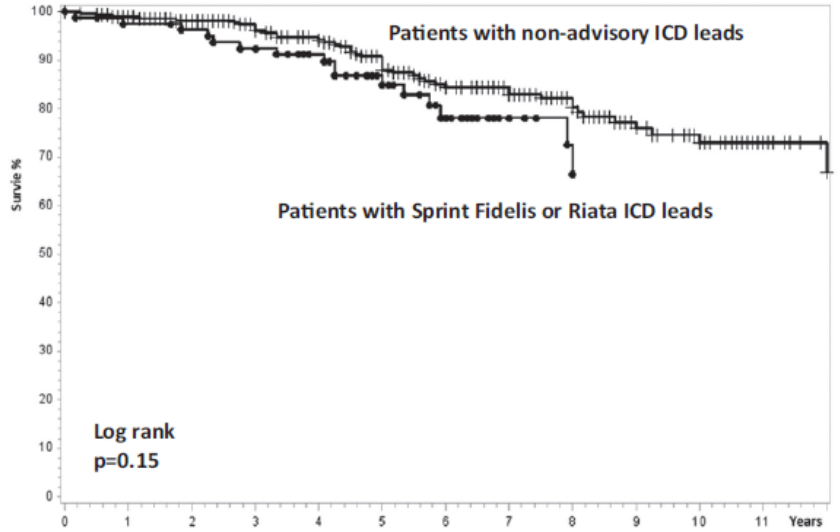
FACULTE DE MEDECINE

Problématiques des sondes de DAI endocavitaires: la rupture

Rate of lead failure depends on lead family design, ranging from 2.9% to 4.5% at 10 years for non-recalled lead families.[1]



	Fidelis	Riata	Durata	Endotak Reliance	Quattro
n	11 709	5900	5538	10 605	16 119
Lead-years	35 300	17 324	6716	27 479	49 689
Incidence (% per year)	2.23	1.17	0.45	0.36	0.29
95% CI	2.08 to 2.39	1.01 to 1.33	0.31 to 0.64	0.30 to 0.44	0.25 to 0.34



Year	0	1	2	3	4	5	6	7	8	9	10	11	12
Non-advisory ICD leads	296	273	245	221	203	165	140	113	87	62	46	25	12
Sprint fidelis or Riata leads	82	79	76	72	66	45	29	17	12	0	0	0	0

Meta-analysis of 17 studies
- 49 871 leads
- 136 509 lead-years

1. Rui Providência et al. J Am Heart Assoc 2015;4:e002418
2. Maisel WM. Pacing and Clinical Electrophysiology. 2004;27:437–442
3. Sacher .Circulation 2013; 128:1937-47

Courtesy from V Probst

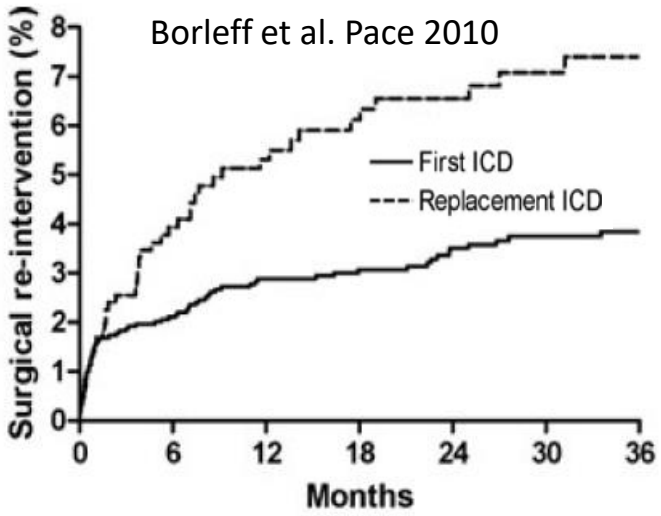
Infection de sondes de DAI endocavitaires

- The **more complex CIED system** implanted the higher infection risk.[3]
- Infection risk is **2–4 × greater** after **device replacement** and **upgrades** compared with primary implants[3]

- Infection commonly **tracks along leads** and/or **causes secondary blood-stream infection and endocarditis**[3]
- Endovascular infections are **associated with high mortality**[2]

Infections and ICD replacement[1]

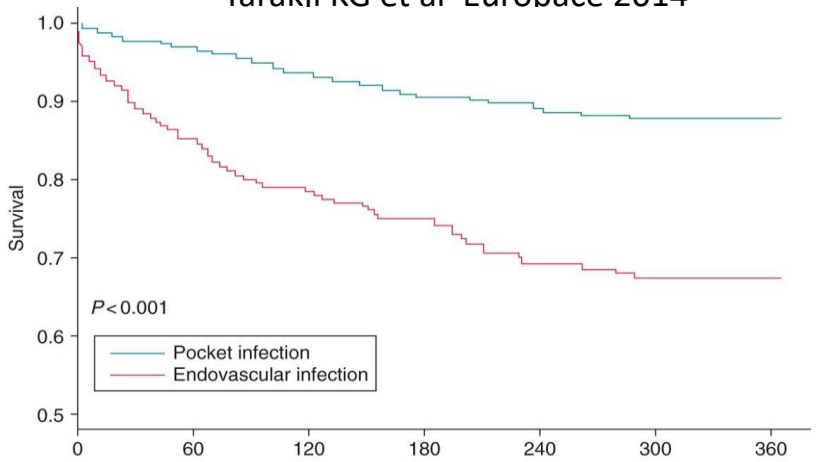
Borleff et al. Pace 2010



ICDs at risk				
First ICD	2415	1748	1299	912
Replacement ICD	746	514	372	235

1-yr mortality following TV-ICD system removal for infection[2]

Tarakii KG et al Europace 2014



Number of patients at risk							
Pocket	289	270	258	245	238	232	230
Endovascular	213	175	159	149	137	132	130

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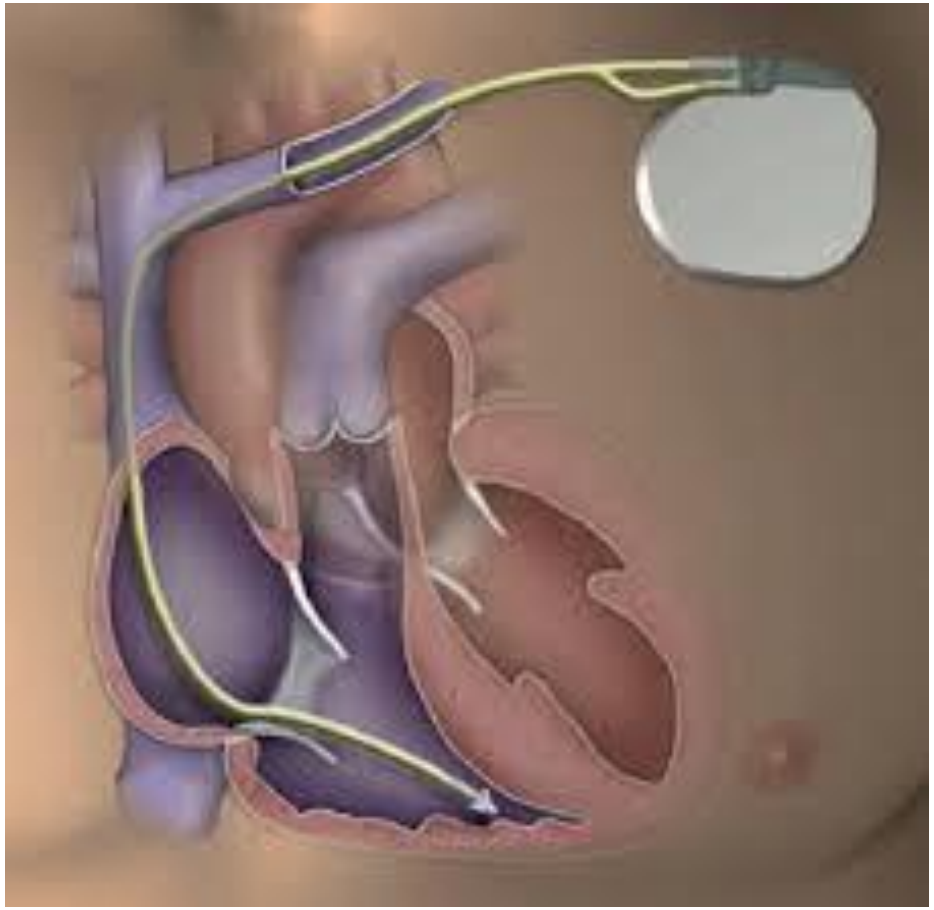
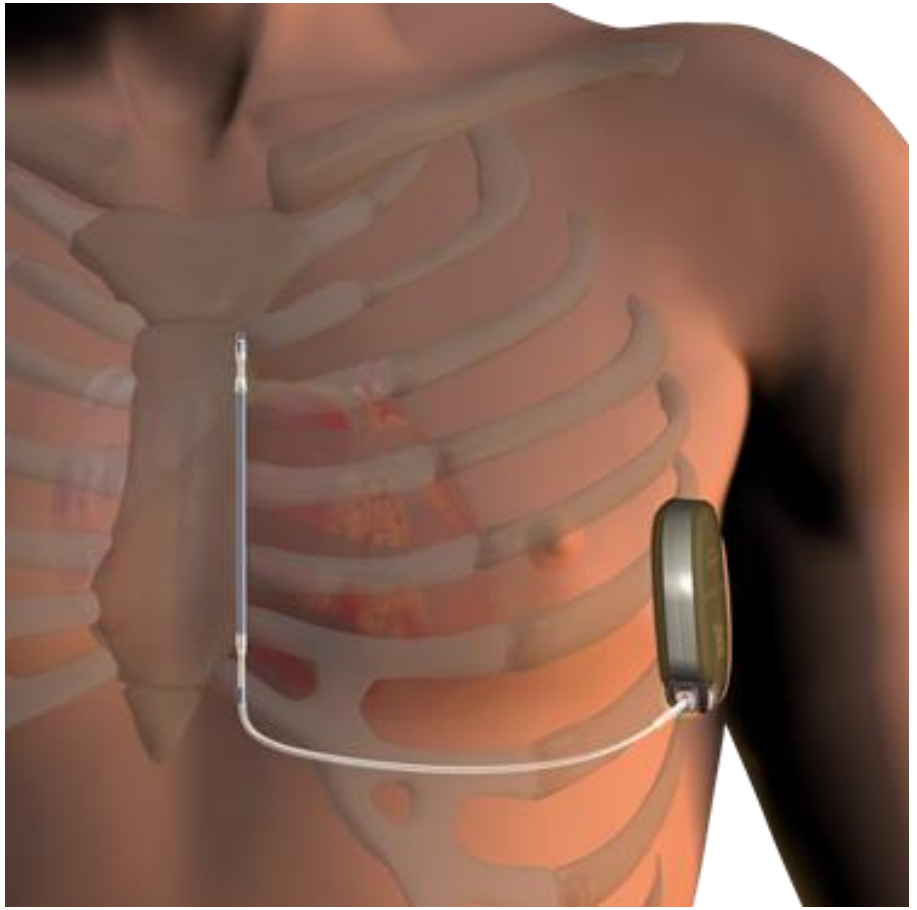
1. Borleff et al. Pace 2010 2. Kirkfeldt RE et al. Eu Hearth J 2013.
2. 2. Tarakji KG et al Europace 2014 3. JC Nielsen et al. European Heart Journal 2015.
3. 3. MC Burke, et al., JACC. 2015; 65:1605–15

Courtesy from V Probst

Sondes endocavitaires : quelle alternative ?










Cameron Health

1ère implantation chronique

Boston

1ère implantation France

Guidelines ESC CMH

Guidelines ESC

Guidelines AHA

2001 2008 2010 2012 2013 2014 2015 2017 2020 2023

Etude princeps NEJM Bardy

Cohorte hollandaise (118)

IDE

Effortless (472)

Pool data analysis (882)

Effortless 3 ans (985)

Registre américain (1637)

PRAETORIAN

UNTOUCHED

2014

3000 S-ICD monde

54 France

2021

100000 S-ICD monde

9000 France

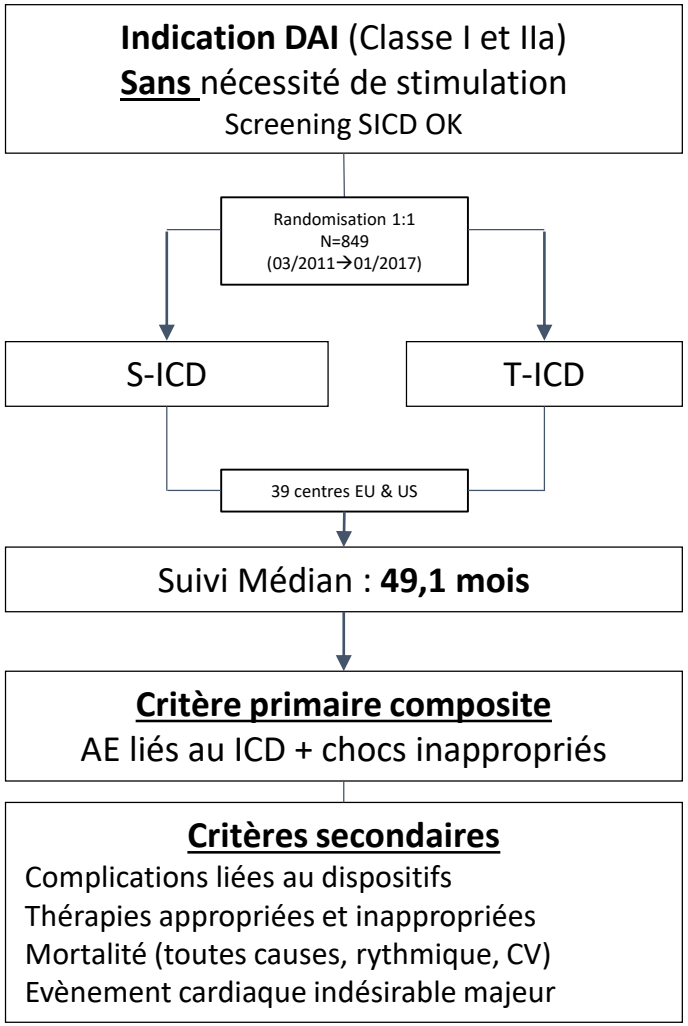
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Subcutaneous or Transvenous Defibrillator Therapy

R.E. Knops, L.R.A. Olde Nordkamp, P.-P.H.M. Delnoy, L.V.A. Boersma, J. Kuschyk, M.F. El-Chami, H. Bonnemeier, E.R. Behr, T.F. Brouwer, S. Kääb, S. Mittal, A.-F.B.E. Quast, L. Smeding, W. van der Stuijt, A. de Weger, K.C. de Wilde, N.R. Bijsterveld, S. Richter, M.A. Brouwer, J.R. de Groot, K.M. Kooiman, P.D. Lambiase, P. Neuzil, K. Vernooy, M. Alings, T.R. Betts, F.A.L.E. Bracke, M.C. Burke, J.S.S.G. de Jong, D.J. Wright, J.G.P. Tijssen, and A.A.M. Wilde, for the PRAETORIAN Investigators*

Méthodologie



- Essai de non infériorité. Analyse de supériorité prévue
- Programmation DAI et S-ICD standardisée

Table II. PRAETORIAN ICD device settings

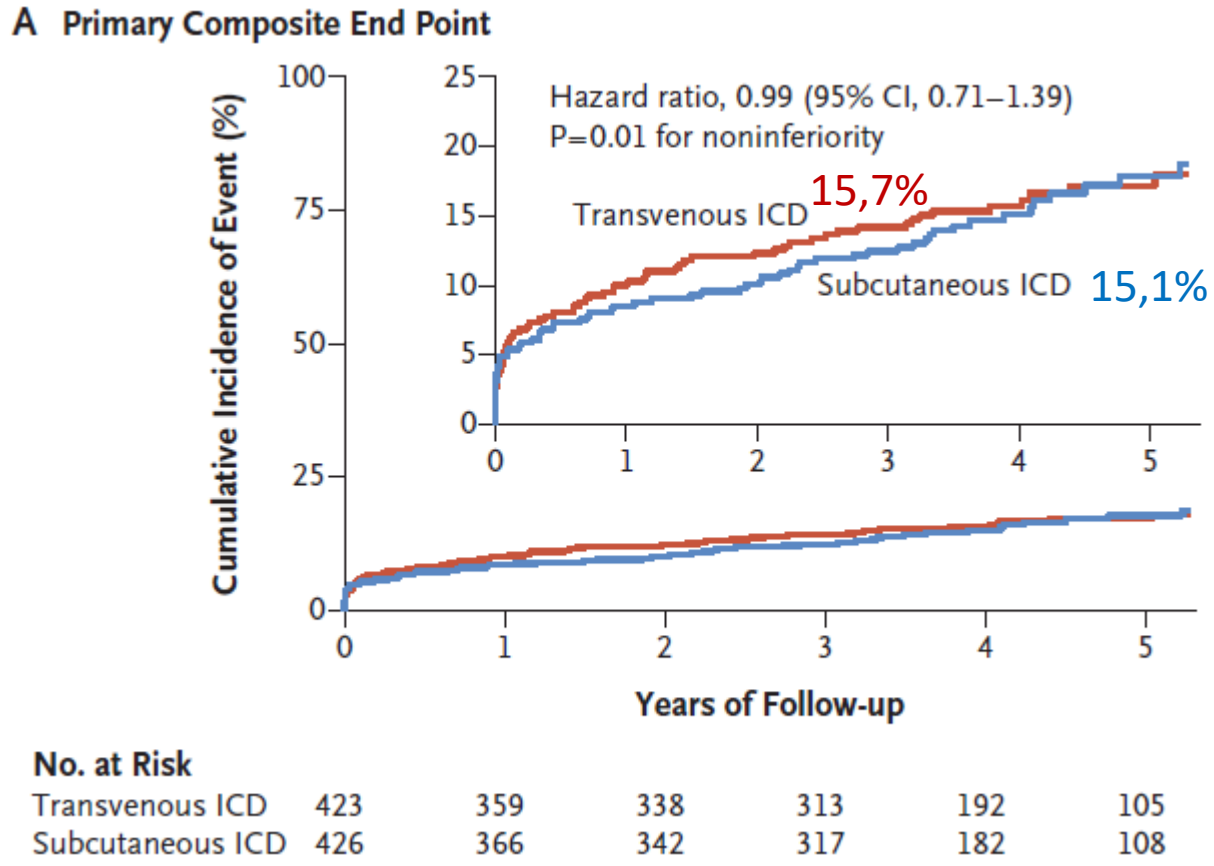
	TV-ICD			S-ICD	
	Monitor zone	**Fast VT zone**	**VF zone**	**Conditional zone**	**Unconditional zone**
Arrhythmia detection zones (beats/min)	>167	>182	>250	>180	>250
Time to initiate therapy (charge for shock or ATP)	11 s	10 s	7.2 s	Fixed (18/24: 6 s)	Fixed (18/24: 4.3 s)
Charge time ICD (expected)		7-8 s		10-12 s	
Time to shock therapy (expected)		14-18 s		14-18 s	
Therapy	No therapy	(1) 1 burst of ATP* (2) Shocks at maximum output	Shocks at maximum output	Shocks at maximum output	Shocks at maximum output
Pacing programming		VVI 40 beats/min		Postshock pacing: "On"	

* Consists of 8 intervals with a pacing length of 88% of the tachycardia length.

Résultats

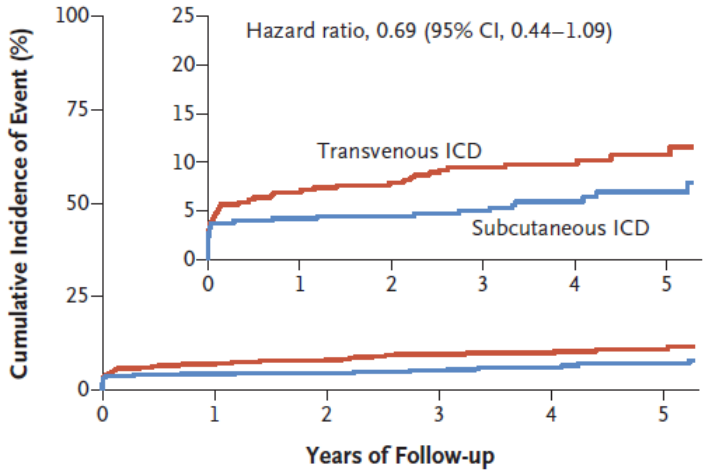
Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Subcutaneous ICD (N=426)	Transvenous ICD (N=423)
Median age (IQR) — yr	63 (54–69)	64 (56–70)
Female sex — no. (%)	89 (20.9)	78 (18.4)
Diagnosis — no. (%)		
Ischemic cardiomyopathy	289 (67.8)	298 (70.4)
Nonischemic cardiomyopathy	99 (23.2)	98 (23.2)
Genetic arrhythmia syndrome	20 (4.7)	18 (4.3)
Hypertrophic cardiomyopathy	15 (3.5)	7 (1.7)
Idiopathic ventricular fibrillation	11 (2.6)	5 (1.2)
Congenital heart disease	3 (0.7)	3 (0.7)
Other†	4 (0.9)	1 (0.2)
Secondary prevention — no. (%)	80 (18.8)	84 (19.9)
Median ejection fraction (IQR) — %	30 (25–35)	30 (25–35)
Mean QRS duration — msec	105±19	105±20
NYHA class — no./total no. (%)		
I	144/423 (34.0)	134/421 (31.8)
II	205/423 (48.5)	223/421 (53.0)
III or IV	74/423 (17.5)	64/421 (15.2)
Median body-mass index (IQR)‡	27.0 (24.5–30.5)	27.9 (25.2–31.7)



AE lié au def et chocs inappropriés

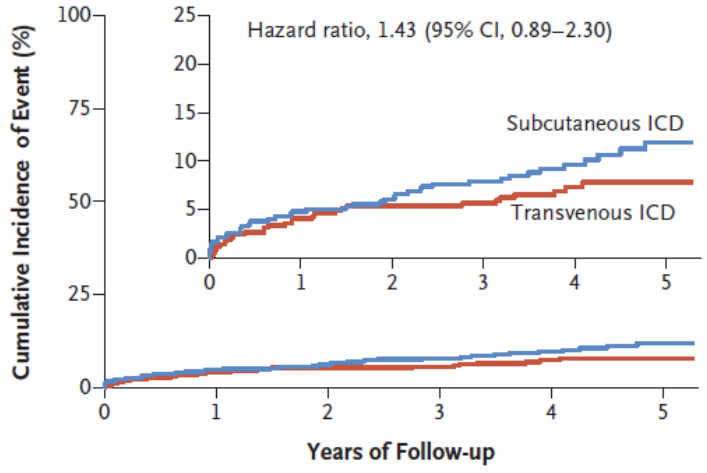
B Device-Related Complications



No. at Risk

Transvenous ICD	423	372	355	331	210	112
Subcutaneous ICD	426	383	362	341	199	121

C Inappropriate Shocks



No. at Risk

Transvenous ICD	423	383	363	340	210	119
Subcutaneous ICD	426	382	358	333	198	117

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	

Table 3. Secondary End Points.*

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)	

Commentaires

- Méthodologie : durée inclusion longue 2011-2017

(connaissance sur le SICD, implantation, programmation, technologie)

- 849 patients inclus. 20% de perdus
- Durée étude 48 mois
- Programmation du def 1 ATP dans zone 180 bpm…
- Bonne nouvelle 9,7 % vs 7,3% chocs inappropriés
- Thérapies sur TV lente considérées comme appropriés: discutable

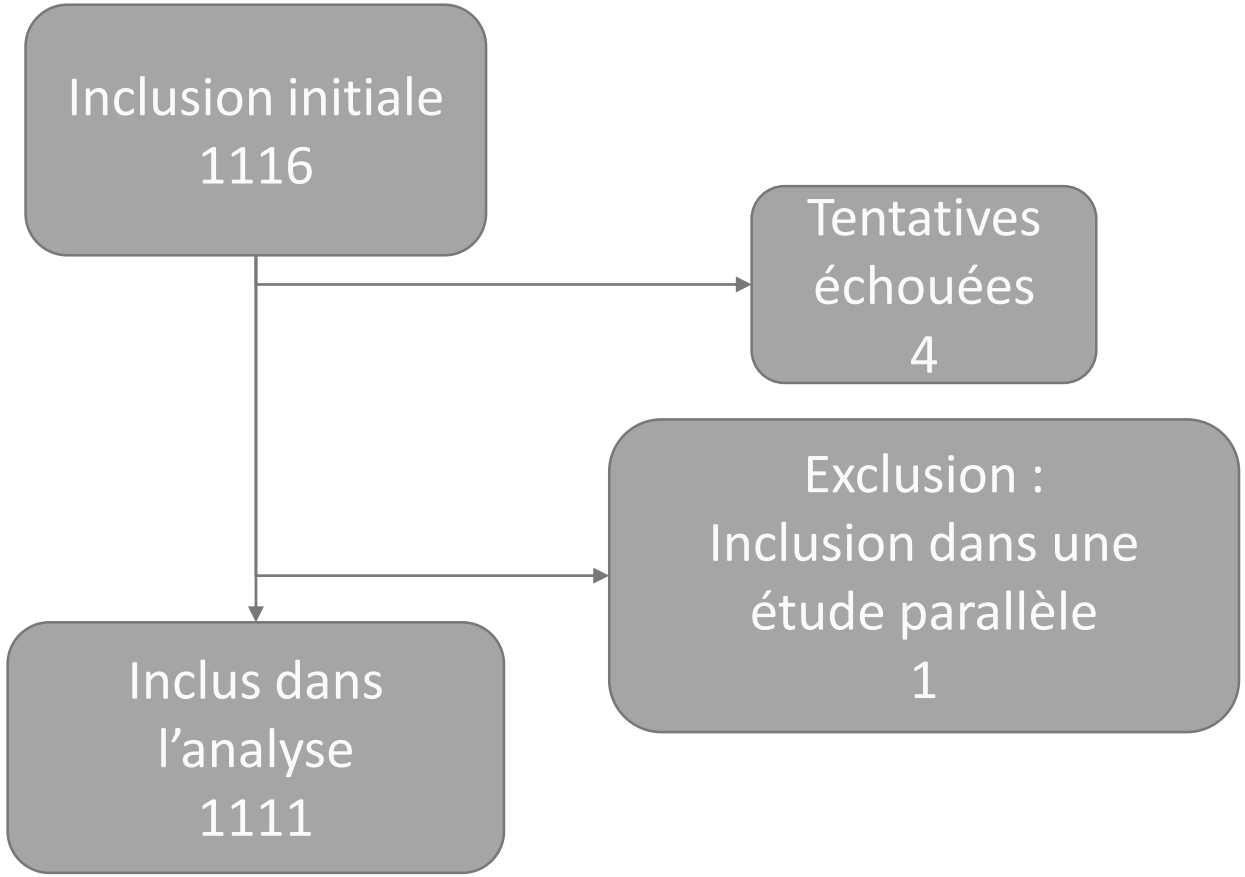
Primary Results from the Understanding Outcomes with the S-ICD in Primary Prevention Patients with Low Ejection Fraction (UNTOUCHED) Trial

Running Title: *Gold et al.; S-ICD UNTOUCHED Trial*

Michael R. Gold, MD, PhD[1]; Pier D. Lambiase, PhD[2]; Mikhael F. El-Chami, MD[3]; Reinoud E. Knops, MD, PhD[4]; Johan D. Aasbo, DO[5]; Maria Grazia Bongiorni, MD[6]; Andrea M. Russo, MD[7]; Jean Claude Deharo, MD[8]; Martin C. Burke, DO[9]; Jay Dinerman, MD[10]; Craig S. Barr, MD[11]; Naushad Shaik, MD[12]; Nathan Carter, MS[13]; Thomas Stoltz, BS[13]; Kenneth M. Stein, MD[13]; Amy J. Brisben, PhD[13]; Lucas V. Boersma, MD, PhD[14]
On behalf of the UNTOUCHED investigators

Circulation 2020;19

Méthologie



- Etude multicentrique, prospective, non-randomisée

- Primo implantation de S-ICD dans 110 Centres (juin 2015 – avril 2018)
- Suivi à 18 mois
- *Programmation : Zone de choc conditionnel : 200 Bpm, zone de choc à 250 Bpm*

- Critères d'inclusion :
  - **Prévention primaire**
  - **FEVG* ≤ 35%**
  - Sans indication de stimulation
  - Eligible au S-ICD selon screening

  - Critère d'évaluation primaire
    - Absence de choc inapproprié à 18 mois : objectif de performance de 91,6% (Dérivé du taux MADIT-RIT des bras B et C: 94,6%)

  - Critères secondaires
    - Taux d'absence de choc toutes causes à 18 mois : objectif de performance de 85,8%
    - Complications liées au système et à la procédure à 30 jours : objectif de performance 93,8%

Gold, et al. Understanding Outcomes with the S-ICD In Primary Prevention Patients with Low Ejection Fraction (UNTOUCHED) Trial Primary Results. LBCT HRS 2020

*FEVG = Fraction d'éjection du Ventricule Gauche

Population

Table 1. UNTOUCHED Patient Characteristics

Patient Characteristics		
Age, years	(n=1116) 55.8±12.4	
Gender, Female, N (%)	286/1116	(25.6)
Black Race, N (%)	239/1020	(23.4)
Height, in	(n=1091) 67.9±4.3	
BMI, kg/m^2	(n=1095) 30.2±7.3	
Prior MI, N (%)	453/1099	(41.2)
Prior valve surgery	36/1114	(3.2)
History of AF, N (%)	142/1116	(12.7)
Ischemic etiology, N (%)	570/1065	(53.5)
LVEF, %	(n=1116) 26.4±5.8	
NYHA class II/III, N (%)	888/1013	(87.7)
High Blood Pressure, N (%)	787/1116	(70.5)
Diabetes, N (%)	364/1116	(32.6)
Kidney Disease, N (%)	160/1116	(14.3)

Table 2. Procedural Characteristics

Procedural Characteristics		
S-ICD screening performed	1111/1111	(100.0)
S-ICD screening performed using AST	305/1110	(27.5)
More than 1 passing vector at screening	705/814	(86.6)
Initial device at implant	1104/1110	(99.5)
Two-incision technique	769/1111	(69.2)
Procedure Duration, minutes	(n=1094) 57.9±27.0	
Gen 3 device with SMART Pass filter	671/1111	(60.4)
DFT performed within first 30 days	911/1111	(82.0)
Adherence to prescribed programming		
At pre-discharge	1064/1082	(98.3)
Throughout the study	1071/1111	(96.4)

Continuous variables are presented as (n=) mean±standard deviation, categorical as frequency n/N (%).
AST = automated screening tool; BMI = body mass index; DFT = defibrillation testing; Gen 3 = Generation 3 device.

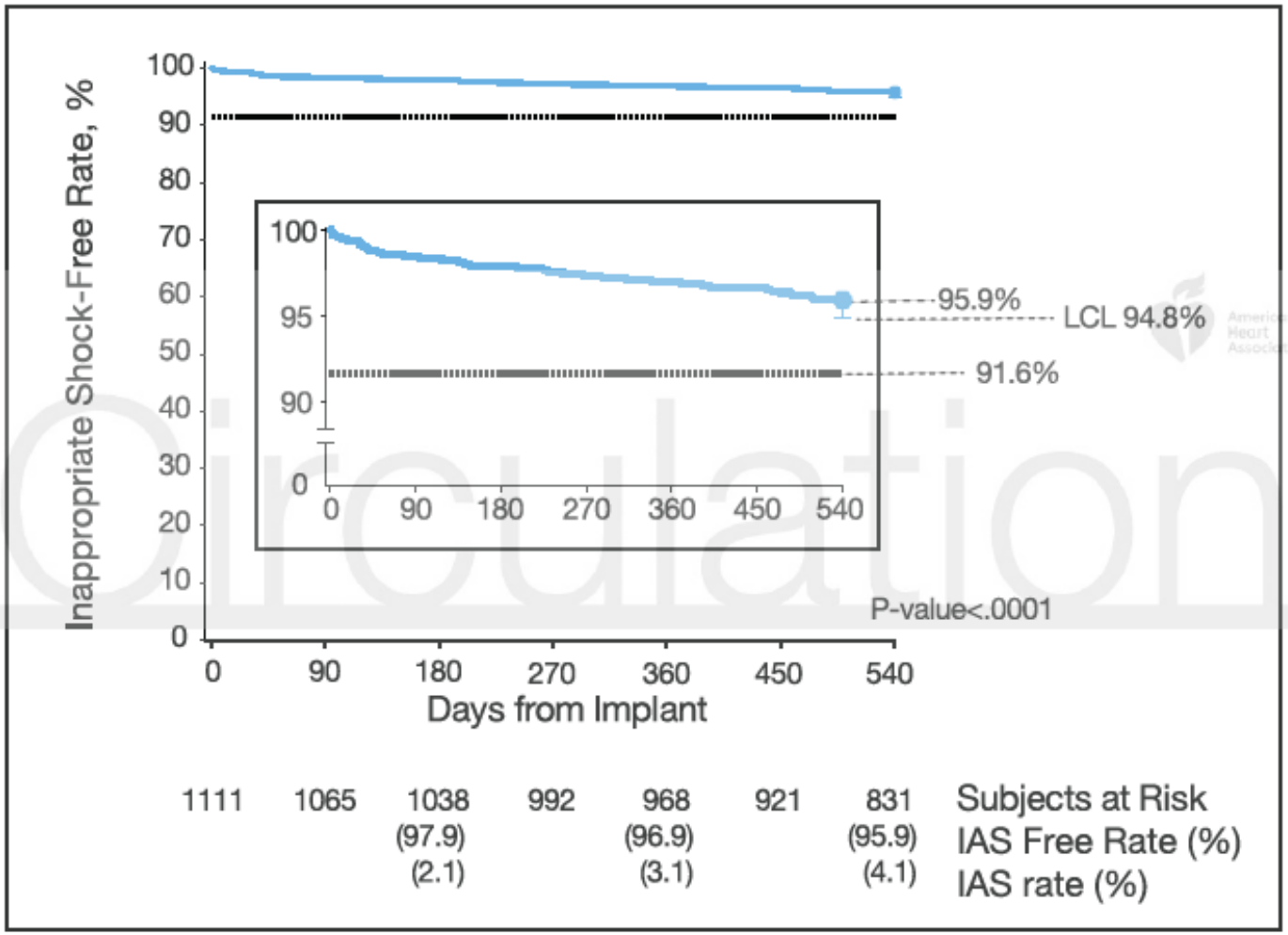


Figure 1. Inappropriate Shock-Free Rate. Kaplan-Meier curve illustrating primary endpoint result: freedom from inappropriate shock at 18 months, compared to a performance goal of 91.6%. Performance goal was derived from the ICD-only inappropriate shock free rate of 94.6% found in MADIT RIT Arms B (high rate) and C (long duration)[17]. Inappropriate shock free rates as well as inappropriate shock rates are provided at 180, 360, and 540 days. IAS = Inappropriate shock.

Absence de chocs inappropriés

3,1% à 1 an de chocs inappropriés

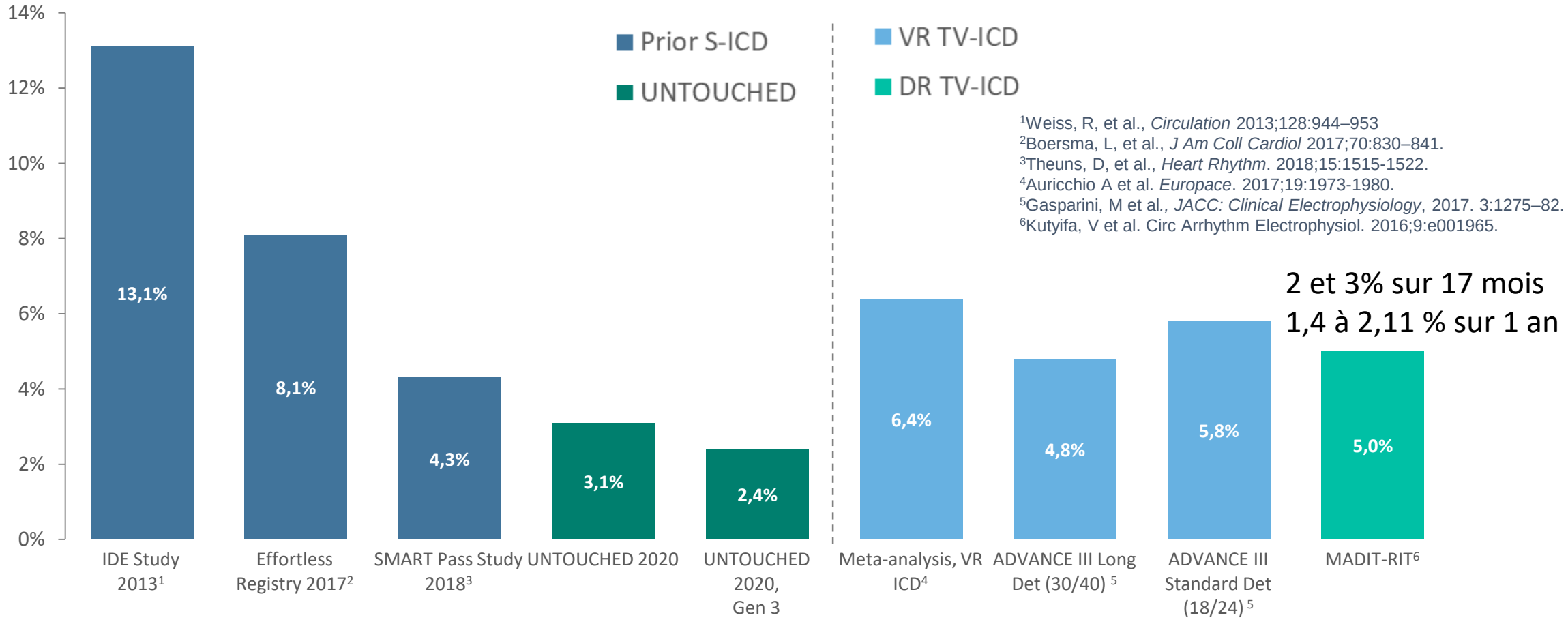
Causes des chocs inappropriés

Table 3. Etiology of Inappropriate Shock

	Total	
IAS Category	**Episodes**	**Subjects**
		N (% of 1111)
Cardiac	**70**	**30 (2.7)**
T-Wave Oversensing	35	18 (1.6)
Other Cardiac Oversensing	14	10 (0.9)
Oversensing of VT/VF below rate zone	21	4 (0.4)
Non-cardiac	**17**	**16 (1.4)**
Myopotential	3	2 (0.2)
Other Non-Cardiac Oversensing	14	14 (1.3)
SVT	**0**	**0 (0)**
Discrimination Error	0	0 (0)
SVT above Discrimination Zone	0	0 (0)
Other	**1**	**1 (0.1)**
Total	**88**	**45 (4.1)**

IAS = inappropriate shock; SVT = supraventricular tachycardia; VT = ventricular tachycardia, VF = ventricular fibrillation.

Taux de chocs inappropriés dans les études S-ICD et T-ICD



[1]Weiss, R, et al., *Circulation* 2013;128:944–953
[2]Boersma, L, et al., *J Am Coll Cardiol* 2017;70:830–841.
[3]Theuns, D, et al., *Heart Rhythm*. 2018;15:1515-1522.
[4]Auricchio A et al. *Europace*. 2017;19:1973-1980.
[5]Gasparini, M et al., *JACC: Clinical Electrophysiology*, 2017. 3:1275–82.
[6]Kutyifa, V et al. Circ Arrhythm Electrophysiol. 2016;9:e001965.

2 et 3% sur 17 mois
1,4 à 2,11 % sur 1 an

Les résultats d'études cliniques différentes ne peuvent être directement comparés et sont donnés à titre d'information uniquement

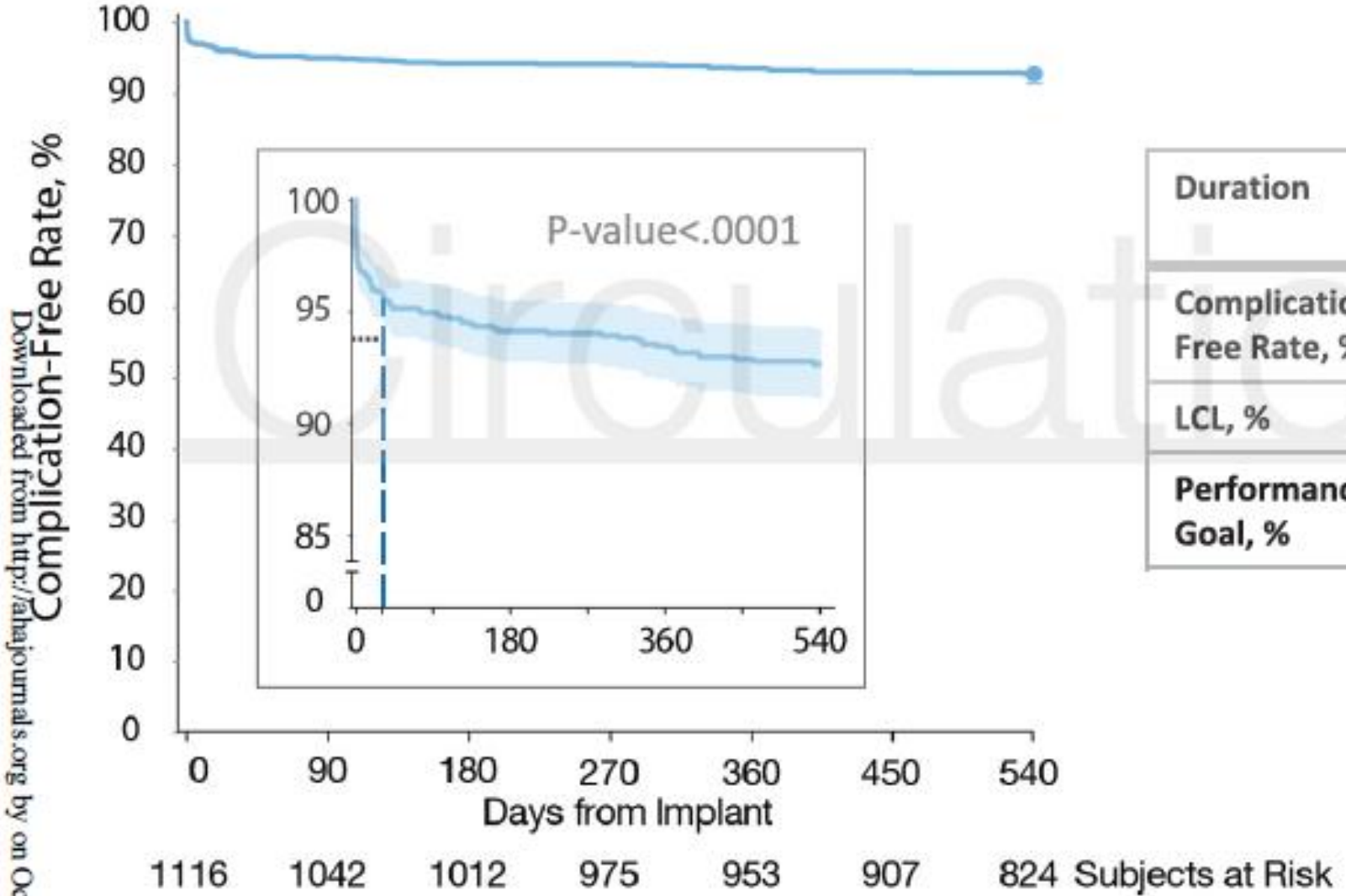
Thérapies appropriés

- Episodes spontanés : n=64 (58 patients)
  - Taux de succès 1er choc : 93.8%
  - Taux de succès global : 98.4%
  - 1 échec (TV à 200 bpm, 1 CEE , échec mais fréquence < 200, non détectée, arrêtée spontanément)

36 patients / 42 épisodes de TV monomorphe
1 à 170 bpm, 25 à 200-230 bpm, 16 > 230 bpm

- Orages rythmiques :
  - 7 sujets
  - 58 épisodes pour 9 orages rythmiques
  - 100% de conversion des orages rythmiques

FU- COMPLICATIONS



Duration	30 days	18 months
Complication Free Rate, %	95.8	92.7
LCL, %	94.6	91.2
Performance Goal, %	93.8	N/A

Classification	Events	N (%)
Sub-optimal position/movement	**12**	**11 (1.0)**
Suboptimal electrode position	3	3 (0.3)
Electrode migration/revision	5	5 (0.4)
Electrode movement	1	1 (0.1)
Electrode erosion	1	1 (0.1)
PG erosion	1	1 (0.1)
PG migration	1	1 (0.1)
Sensing/device function	**12**	**12 (1.1)**
Inappropriate therapy / Oversensing	7	7 (0.6)
Device shocked 5 times before conversion	1	1 (0.1)
Premature cell battery depletion – PG	3	3 (0.3)
Random component failure – Therapy available	1	1 (0.1)
Conversion test-related	**10**	**10 (0.9)**
Out of Range shock impedance – Electrode	1	1 (0.1)
Unable to convert VT/VF with S-ICD	9	9 (0.8)
Device system infection	**12**	**12 (1.1)**
Device system infection (acute)	8	8 (0.7)
Device system infection (>30d post implant)	4	4 (0.4)
Post-op healing / pain management	**23**	**23 (2.1)**
Electrode suture discomfort	1	1 (0.1)
Device system discomfort	4	4 (0.4)
Post-surgical wound discomfort PG site	4	4 (0.4)
Incisional/Superficial infection	5	5 (0.4)
Suspected infection – Incisional/Superficial	1	1 (0.1)
Hematoma – PG pocket	4	4 (0.4)
Inadequate healing of incision site	2	2 (0.2)
Physical trauma	2	2 (0.2)
Other procedure-related	**12**	**12 (1.1)**
Adverse reaction – Respiratory	1	1 (0.1)
Adverse reaction – Hypotension	3	3 (0.3)
Adverse reaction – Medication/Anaphylactic shock	1	1 (0.1)
Adverse reaction – HF symptoms	1	1 (0.1)
Acute blood loss	1	1 (0.1)
postoperative urinary retention	1	1 (0.1)
Hemodynamic instability – DFT testing	1	1 (0.1)
Fascial defect closure	1	1 (0.1)
Suture revision	1	1 (0.1)
Syncope	1	1 (0.1)
Other patient-related	**2**	**2 (0.2)**
Outcome of elective MV and LAA closure surgery	1	1 (0.1)
Weight loss	1	1 (0.1)

Pas de fracture de sonde

12 infections

0 bactériémie

Table 4. Reasons for Device Explant/Inactivation

Reason for device explant/inactivation	Number of Patients
Death, organ transplant, LVAD implant, or palliative/hospice care	58
Subject Death	49
Target Organ Transplant	4
Hospice Care	3
Palliative Care	1
LVAD placed	1
Pacing Need	4
Upgraded to CRT	2
Required ATP	2
Required Brady Pacing	0
Post op healing/infection	17
Infection	12
Discomfort	3
Erosion	2
Other	15
Elective Decision	5
Premature Battery Depletion	2
Suspected Device Malfunction	3
Inappropriate Shocks	3
Failed Conversion Testing at Implant/Predischarge	1
Migration/Displacement	1
Grand Total	**94**

< 0,5% de conversion en matériel endocavitaire

Intérêt UNTOUCHED

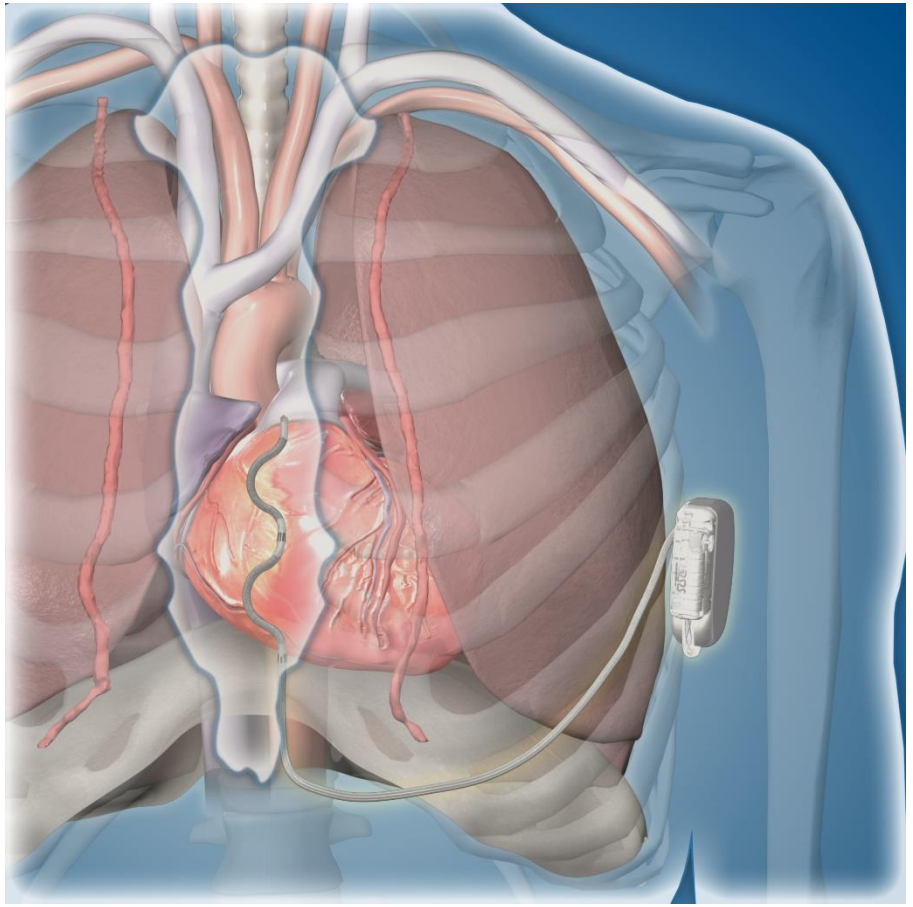
- Population / vraie vie
- Volume mais suivi court
- Etude récente
- Patients graves avec cardiopathie

- Valide concept du SICD dans cette population en terme efficacité/ taux acceptable de CI et de complications
- Conforte sécurité des 2 zones (200/250 bpm)

Concept: défibriller sans sonde endocavitaire

S-ICD: Subcutaneous Defibrillator

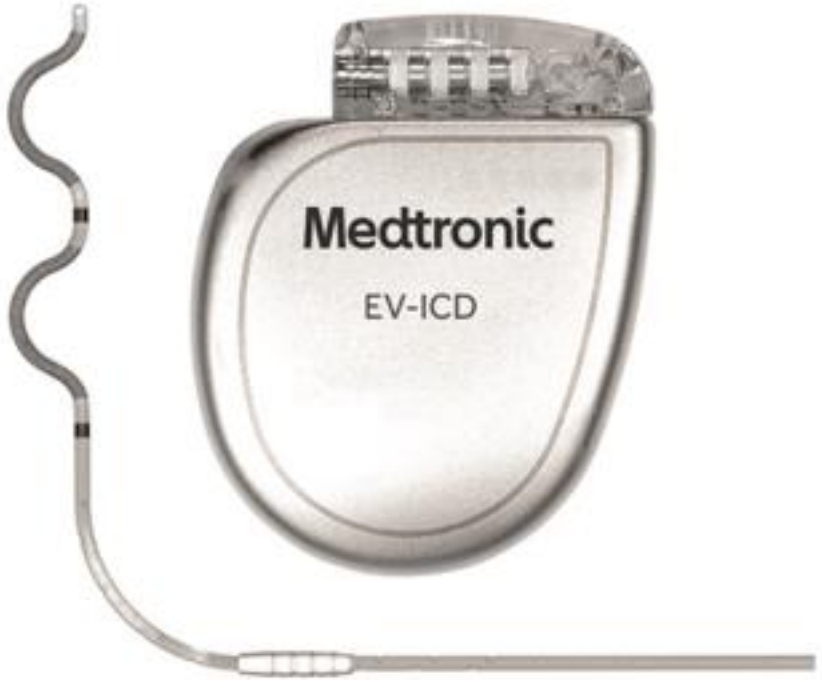
EV-ICD: Extravascular Defibrillator



Etudes EV-ICD

- 20 patients en chronique
- Succès défibrillation 90% avec marge 10J
- Seuil médian défibrillation 15 J
- Amplitude onde R: 3.4 +/_2.0 mV,
- Amplitude moy en FV 2.8 +/_ 1.7 mV,
- Stimulation possible dans 95% at ≤10 V.
- AE < 90 jours: 1 thérapie inappropriée (P wave OS), 2 inconforts respiratoires, 3 problèmes mineurs de cicatrice
- AE > 90 jours: 1 patient explanté pour échec de défibrillation à 30 J
- 1 patient TV échec ATP choc efficace
- Ressenti de la stimulation

Crozier. J Am Coll Cardiol EP 2020;6:1525–36



- 400 patients
- Multicentrique non randomisée
- FU 3,5 ans
- EP : défibrillation à l'implantation
- Autres objectifs: pacing, ATP, chocs appropriés et inappropriés.

ORIGINAL - DEVICES

WILEY

The extravascular implantable cardioverter-defibrillator: The pivotal study plan

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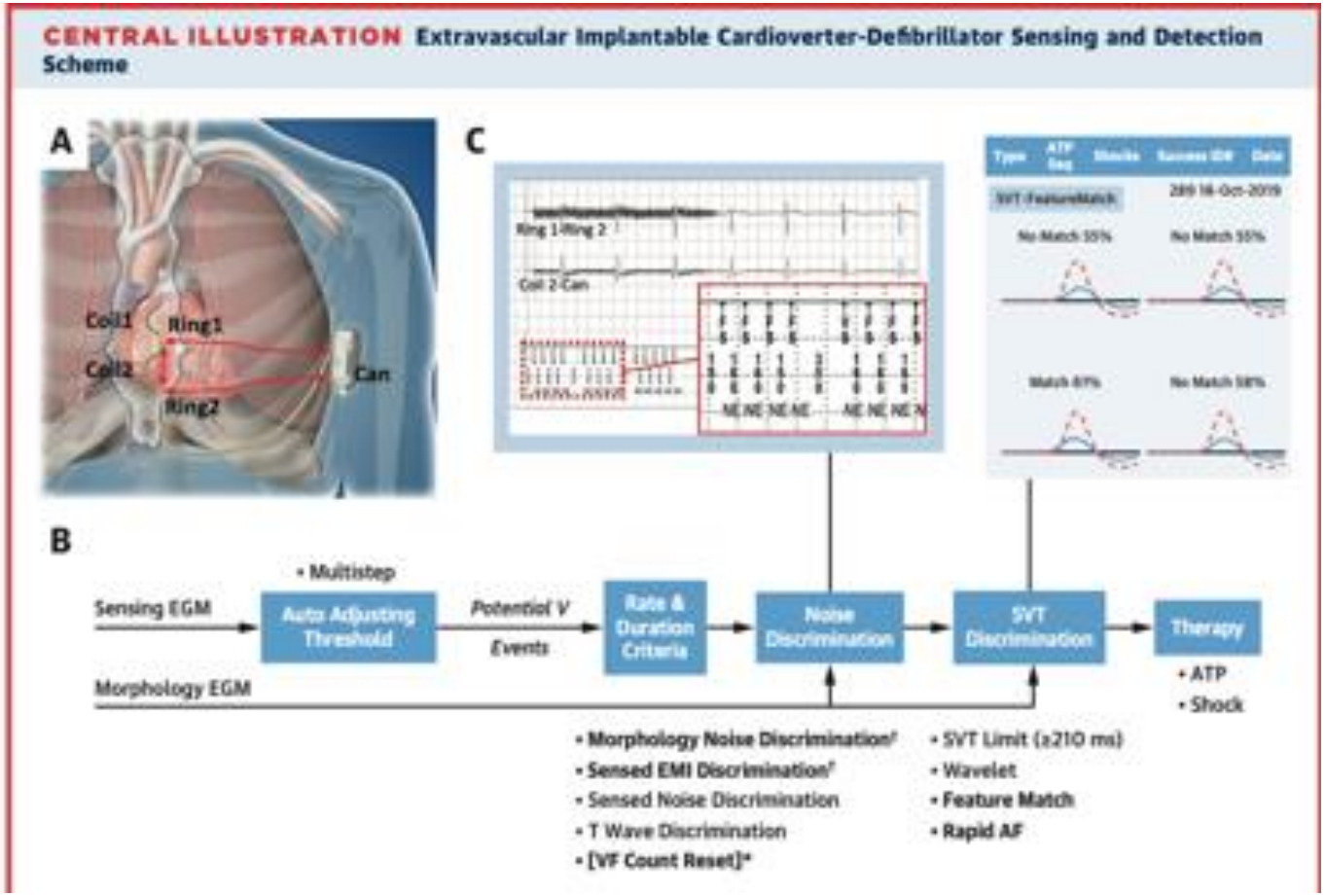
Résultats préliminaires

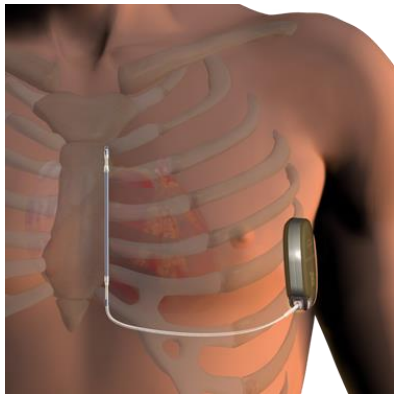


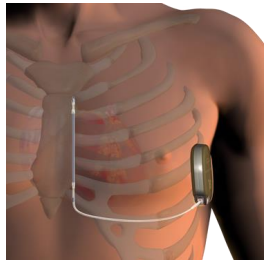
Surdétection fréquente mais non soutenue
TRSV bien discriminés
Détection VF pour sensibilité 0,3 mV
Déterminer meilleur vecteur pour écoute
Effets des modifications des postures

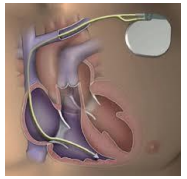
Swerdlow. Am Coll Cardiol EP 2021

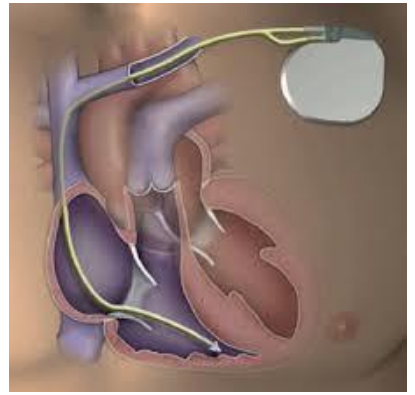
Pour qui ?

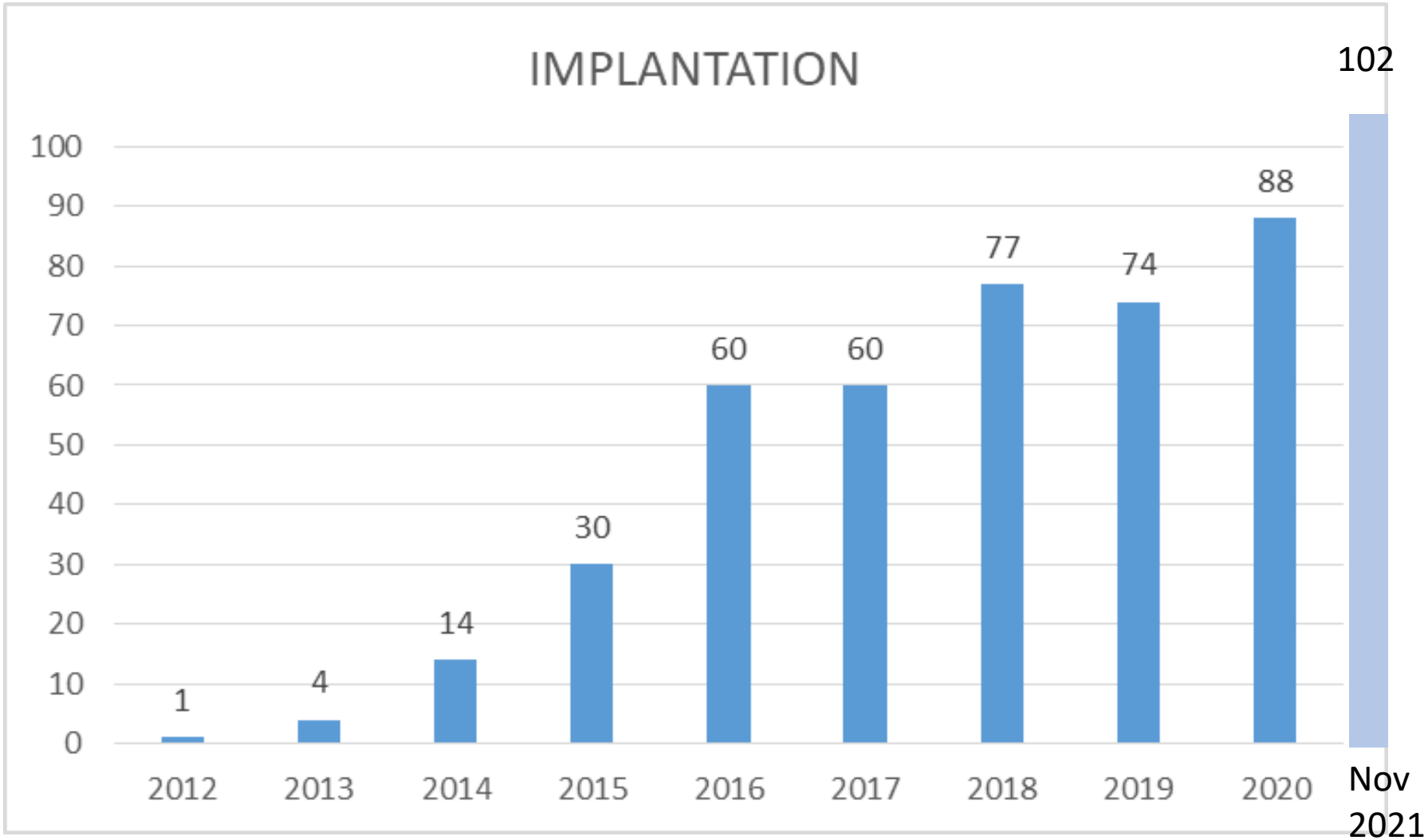
< 50 ans	50– 70 ans	> 70 ans







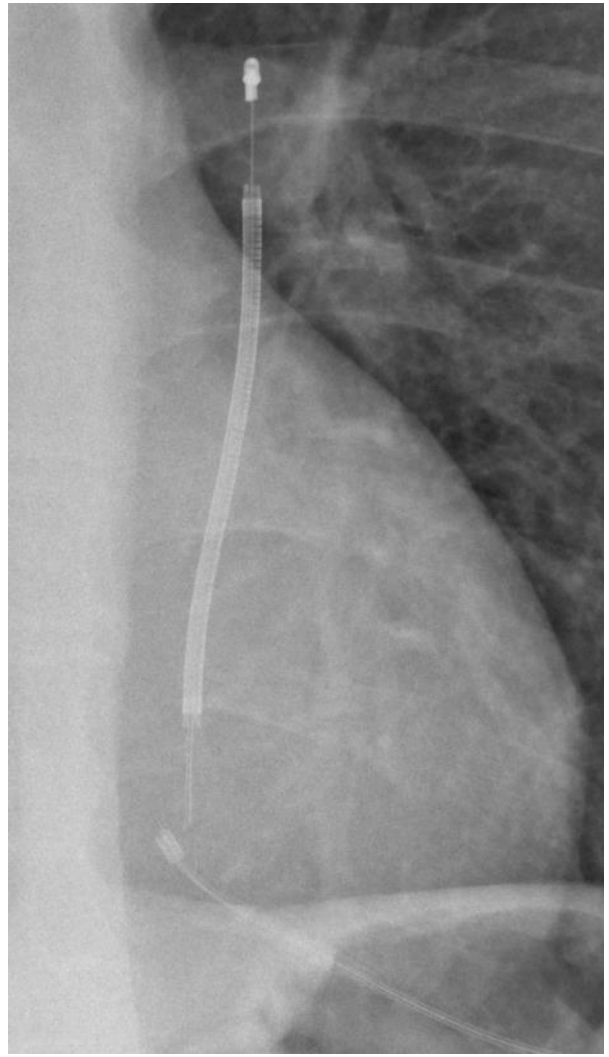




En 2020, 239 primo def , 35% de SICD, 21% de Vr, 17% de Dr, 27% de CRT
En nov 2021 , 221 primo, 33% de SICD, 31% de Vr,, 15% Dr, 20% de CRT
2020 5 remplacement SICD, 29 en 2021

Notre expérience

- 5 infections, aucune bactériémie
- Explantations : 2 pour intolérance, 0 pour des pb de détection, 0 pour des échecs de thérapies, 5 pour des CRT
- Changements de boitier pour recall (court-circuit ou batterie)
- OR/TV monomorphes ablation par RF
- Détection et stabilité du signal
- 1 rupture de sonde



PERSPECTIVES

- Praetorian XL
- Praetorian DFT
- Registre français
- EV-ICD

- Défits du défibrillateur sans sonde endocavitaire
  - Progresser sur la détection (ondes T, stabilité du signal, double comptage des TV)
  - Taille et durée de vie du boitier
  - Fiabilité du matériel (sondes et boitier)

Avenir

- Solution modulaire
- Des alternatives

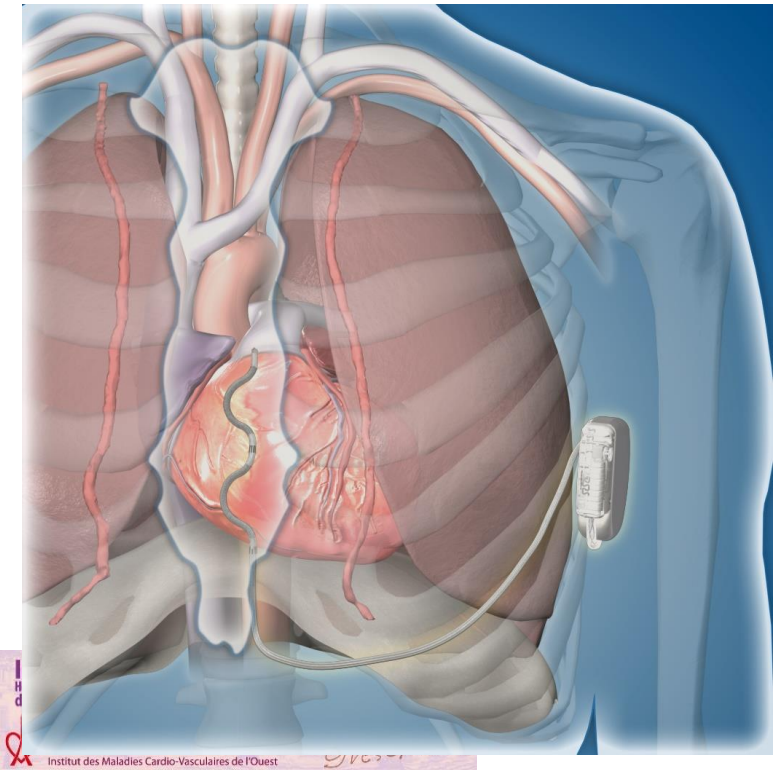
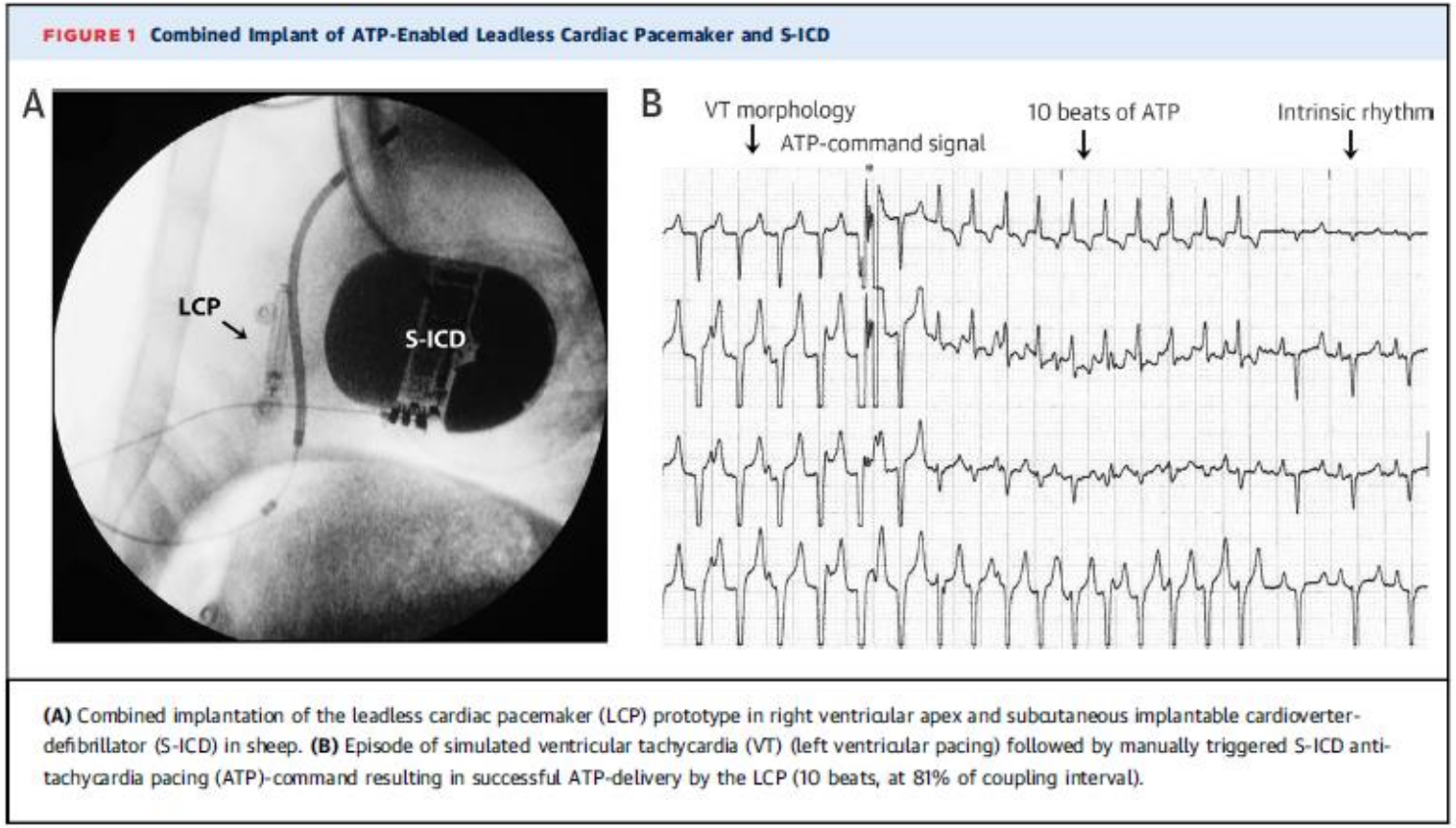


FIGURE 1 Combined Implant of ATP-Enabled Leadless Cardiac Pacemaker and S-ICD



(A) Combined implantation of the leadless cardiac pacemaker (LCP) prototype in right ventricular apex and subcutaneous implantable cardioverter-defibrillator (S-ICD) in sheep. **(B)** Episode of simulated ventricular tachycardia (VT) (left ventricular pacing) followed by manually triggered S-ICD anti-tachycardia pacing (ATP)-command resulting in successful ATP-delivery by the LCP (10 beats, at 81% of coupling interval).

Tjong.JACC 2016;67:1833-70