Collège National des Cardiologues des Hôpitaux

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SESSION

« Comment prévenir les infections de dispositifs cardiaques implantables ? "

Antoine Da Costa
CHU Saint Etienne
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Avec le soutien institutionnel de

Collège
National des
Cardiologues des
Hôpitaux

Données épidémiologiques

- Of **4 144 683** device-related procedures, **85 203 (2.06%)** were associated with device related infections (DRI).
- From 2000 through 2012, procedures related to DRI increased from **1.45% to 3.41% (P < .001).**
- The risk of infection for CRT devices was the highest, **peaking in 2012 (adjusted odds ratio [OR] 2.43, P < .001).**

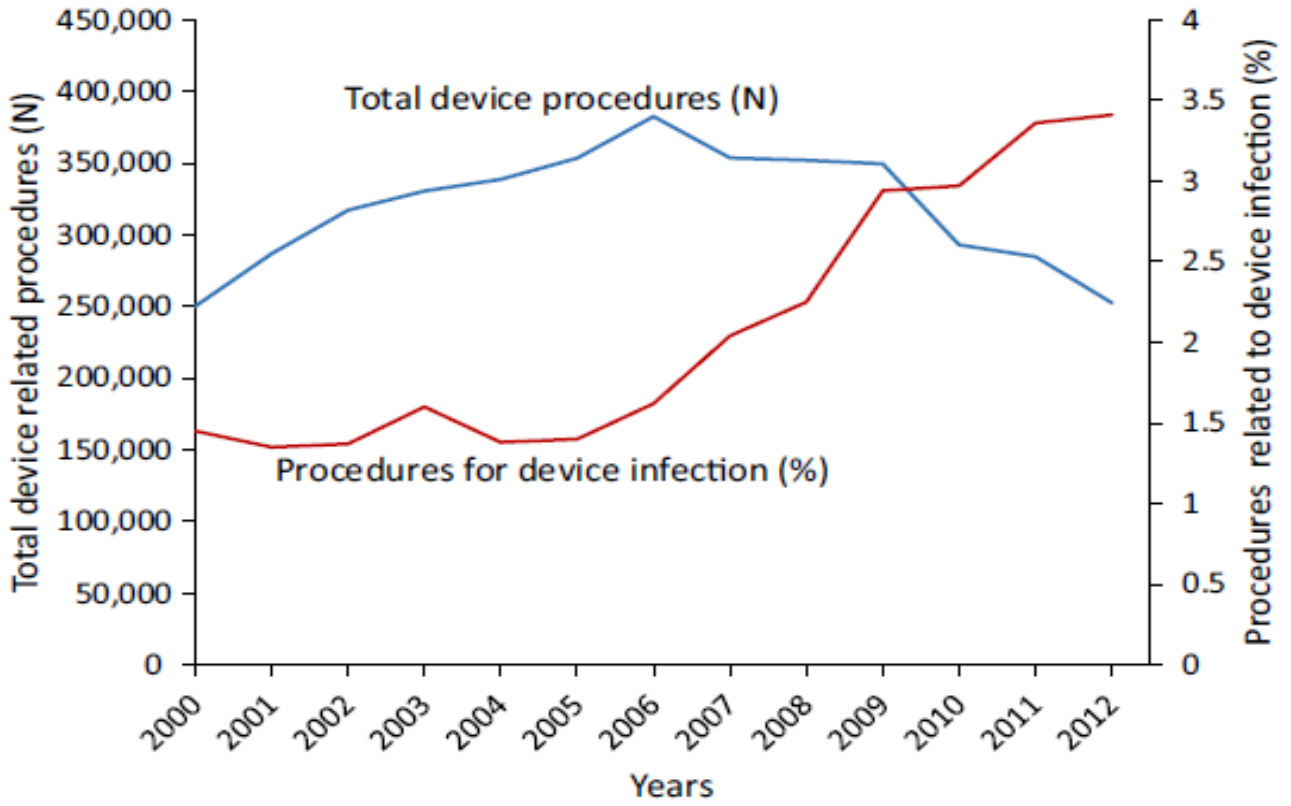


Figure 1 Yearly trend of device-related procedures. Trend of total number of device-related procedures (left axis) vs percentage of procedures due to device infections (right axis).

Cardiac implantable electronic device infections: Who is at greatest risk? Parijat Saurav Joy, MD. Heart Rhythm 2017; 14:839–845.

Cardiac implantable electronic device infections: Who is at greatest risk? Parijat Saurav Joy, MD. Heart Rhythm 2017; 14:839–845.

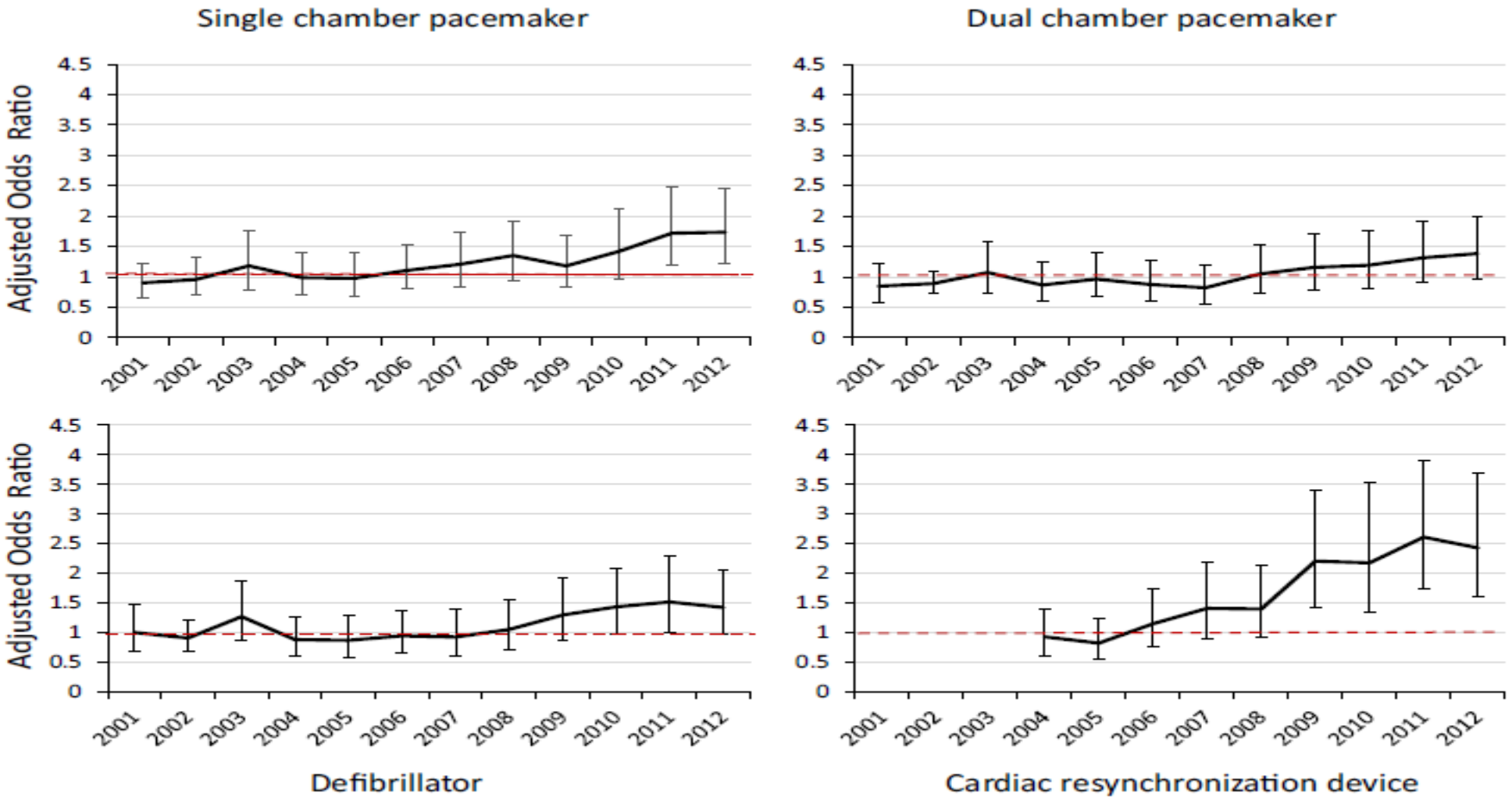


Figure 2 Risk of infection vs type of device. Trend of adjusted odds ratio for device removal due to infection, according to device types. Reference year is 2000 for all device types except cardiac resynchronization devices, which have a reference year of 2003.

Cardiac implantable electronic device infections: Who is at greatest risk? Parijat Saurav Joy, MD. Heart Rhythm 2017; 14:839–845.

Table 3 Outcomes for cardiac device–related procedures by device type due to infection and without infection

	Single-chamber pacemaker		Dual-chamber pacemaker		Resynchronization device		Defibrillator	
	Without infection	With infection	Without infection	With infection	Without infection	With infection	Without infection	With infection
Mortality, %	1.8	3.4	1	2.1	0.9	2.4	0.7	2
Home health	14.9	30.8	12.8	30.9	11.2	37	9.8	33.7
Nursing home	24	31.4	15.9	24.9	8.1	20.1	8.1	17.6
Others	0.1	0.3	0.1	0.2	0.1	0.3	0.2	0.2
LOS (IQR)	5 (2–8)	10 (6–16)	4 (2–7)	9 (6–16)	2 (1–7)	11 (8–18)	4 (1–8)	12 (7–19)

Disposition = discharge disposition; IQR = interquartile range; LOS = median inpatient length of stay.

- Charges associated with CRT DRIs increased nearly 2-fold in a decade.
- Higher inpatient mortality related to device infection were stroke (OR: 3.19, P , .001), end-stage renal disease (OR: 2.91, P , .001), malnutrition (OR: 2.67, P , .001), cirrhosis (OR: 2.05, P 5 .001), and organ transplantation(OR: 2.16, P , .001).

Considérations générales des infections de PM/DAI

- **Taux d'infections a plus que doublé**

- **Facteurs explicatifs:**
  - patients plus âgés
  - co-morbidités
  - procédures plus longues
  - changement de boitiers
  - up-grading
  - reprises chirurgicales
  - résistances accrues aux staphylocoques coagulases négatifs et dorés

Épidémiologie

- **Prévalence des infections secondaires aux DI:**
  - 1% PM
  - 2% DAI or remplacement
  - 3.4% to 7% pour les CRT (cardiac resynchronisation therapy device)
  - études prospectives:
    - CRT-ICD (**RAFT N Engl J Med 2010**): **2.4% avec le CRT-D vs. 1.8% DAI seul**
    - **DANISH study 2016** (device infection): **4.9% in the ICD** group and **3.6% in the control group** (CRT-P) (P=0.29).

- **Prévalence des EI sur dispositifs:**
  - 0.25 % avec une haute morbi-mortalité
  - 10% to 20% des infections de DI

Grammes JA et al. Percutaneous PM and ICD lead extraction in 100 patients with intracardiac vegetations defined by TEE. J Am Coll Cardiol 2010; 55; 886-94.

Incidence of device-related infection in 97 750 patients: clinical data from the complete Danish device-cohort (1982-2018). Thomas Olsen et al. European Heart Journal (2019) 40, 1862–1869

Table 2 Incidence and incidence rate of device-related infection in the Danish CIED population 1982–2018

Variable	Devices	Device years	Events	Overall incidence			Incidence rate /1000 DY		
					95% CI			95% CI	
Total	128 045	566 275	1827	1.43%	1.36	1.49	3.23	3.08	3.38
Sex									
Female	51 484	241 524	505	0.98%	0.90	1.07	2.09	1.92	2.28
Male	76 561	324 750	1322	1.73%	1.64	1.82	4.07	3.86	4.30
Operation & Device Type									
Pacemaker									
Total	100 374	460 196	1194	1.19%	1.12	1.26	2.59	2.45	2.75
First	79 318	364 744	744	[illegible]	0.87	1.01	2.04	1.90	2.19
Replacement	17 265	77 742	359	2.08%	1.87	2.30	4.62	4.16	5.12
Up-/downgrade	3791	17 708	91	2.40%	1.94	2.94	5.14	4.18	6.31
ICD									
Total	16 718	69 766	320	1.91%	1.71	2.13	4.59	4.11	5.12
First	12 037	52 040	200	[illegible]	1.44	1.91	3.84	3.35	4.41
Replacement	3959	15 015	92	2.32%	1.88	2.84	6.13	4.99	7.52
Up-/downgrade	722	2711	28	3.88%	2.59	5.56	10.33	7.13	14.96
CRT-P									
Total	4630	15 848	101	2.18%	1.78	2.64	6.37	5.24	7.75
First	2991	10 965	48	[illegible]	1.19	2.12	4.38	3.30	5.81
Replacement	769	2249	26	3.38%	2.22	4.91	11.56	7.87	16.97
Up-/downgrade	870	2632	27	[illegible]	2.05	4.48	10.26	7.03	14.96
CRT-D									
Total	6323	20 464	212	3.35%	2.92	3.83	10.36	9.05	11.85
First	3386	12 131	82	2.42%	1.93	3.00	6.76	5.44	8.39
Replacement	1339	3537	67	5.00%	3.90	6.31	18.94	14.91	24.07
Up-/downgrade	1598	4795	63	3.94%	3.04	5.02	13.14	10.26	16.82

Facteurs de risques associés aux infections de DI

- **Etude People** (Klug et al. Circulation 2007):
  - Stimulation temporaire
  - Hématomes
  - Reprise chirurgicale
  - Absence d'antibioprophylaxie
  - Fièvre dans les 24 heures

- **CRT study infections evaluation** (Romeyer C et Da Costa A. et al. Eur Heart J 2010) :
  - Insuffisance rénale avec dialyse
  - Reprise chirurgicale
  - Type de dispositif: infections sur DAI > PM
  - Durée de la procédure

Facteurs de risques associés aux infections de DI

Facteur de risque prédéfini	FDR en analyse multivariée	Type de dispositif	OR (95% IC)
Insuffisance cardiaque	CHF	PM, DAI	2.57 (1.23-4.51)
Insuffisance rénale	idem	PM, DAI	5.46 (1.99-10.6)
Dialyse	idem	PM, DAI, CRT	4.64 (2.4-47.6)
Anticoagulants	Anticoagulant oral	PM, DAI, CRT	2.82 (1.2-6.7)
Corticoides	idem	PM, DAI	13.9 (1.3-151)
Reprise, Remplacement	**Remplacement** **Reprise**	**PM, DAI** **PM, DAI, CRT**	**2.24 (1.04-4.83)** **3.67 (1.51-8.96)**
Entrainement provisoire	SEE	PM, DAI, CRT	2.46 (1.09-5.13)
> 2 électrodes	**> 2 vs 2 électrodes**	**PM**	**5.41 (1.44-20.3)**
	>2 vs 1 électrode	PM	5.64
Réintervention	**idem**	**PM, DAI, CRT**	**15.04 (6.7-33.73)**

Incidence of device-related infection in 97 750 patients: clinical data from the complete Danish device-cohort (1982-2018). Thomas Olsen et al. European Heart Journal (2019) 40, 1862–1869

Mécanismes responsables de l'infection

- **Contamination cutanée au moment de l'implantation ++++**

- **Contamination après la chirurgie:**
  - Problèmes de cicatrisation(suture)
  - Hématomes (anticoagulation)
  - Contamination locale au cours des soins locaux

- **Contamination par érosion cutanée:**
  - Taille du dispositif
  - Localisation pré ou rétro pectorale
  - Status cutané ou pathologies de peau
  - Diabète; corticostéroides

- **Infections secondaires:**
  - Infections liées au cathéters
  - septicémies

Microbiology. Role of the Preaxillary Flora in Pacemaker Infections. A Prospective Study

Species	Skin	Pocket	Generator
Staphylocoques	**150**	**45**	**32**
St. Epidermidis	**71**	**28**	**22**
St. Aureus	**8**	**0**	**1**
St. Schleiferi	**2**	**2**	**1**
Micrococcus	0	2	1
Aerococcus	0	0	1
Enterococcus	7	0	0
Streptococcus viridans	7	3	1
Corynebacterium	0	4	1
Serratia Marcecens	1	0	0
Total bacterial isolates	**175**	**56**	**36**
Total Positive samples	**88.3%**	**48%**	**37.1%**

Da Costa A et al. Circulation 1998; 97: 1791-5

Microbiology. Role of the Preaxillary Flora in Pacemaker Infections. A Prospective Study. Da Costa A et al. Circulation 1998; 97: 1791-5.

Patient No.	Age	Sexe	Clinical Presentation	Bacteriological results at the implantation	Bacteriological results at the time of the complication
1	87	H	Skin erosion bacteremia (16 mo)	St. Schleiferi device	Blood culture: St Schleiferi
2	62	H	Bacteremia (4 mo)	St. Schleiferi pocket	Blood culture: St Schleiferi
3	66	H	Wound abcess (10 mo)	St. Schleiferi pocket	St. Aureus local
4	72	H	Skin erosion (1 mo)	Coagulase negative staph. (skin)	Local Coagulase negative staph.
5	87	F	Skin erosion (9 mo)	St. haemolyticus	Negative culture
6	76	H	Skin erosion (29 mo)	St. Schleiferi pocket	Local St. Schleiferi

Microbiology. Role of the Preaxillary Flora in Pacemaker Infections. A Prospective Study. Da Costa A et al. Circulation 1998; 97: 1791-5

HindIII restriction patterns of rDNA from Staphylococcus schleiferi isolates

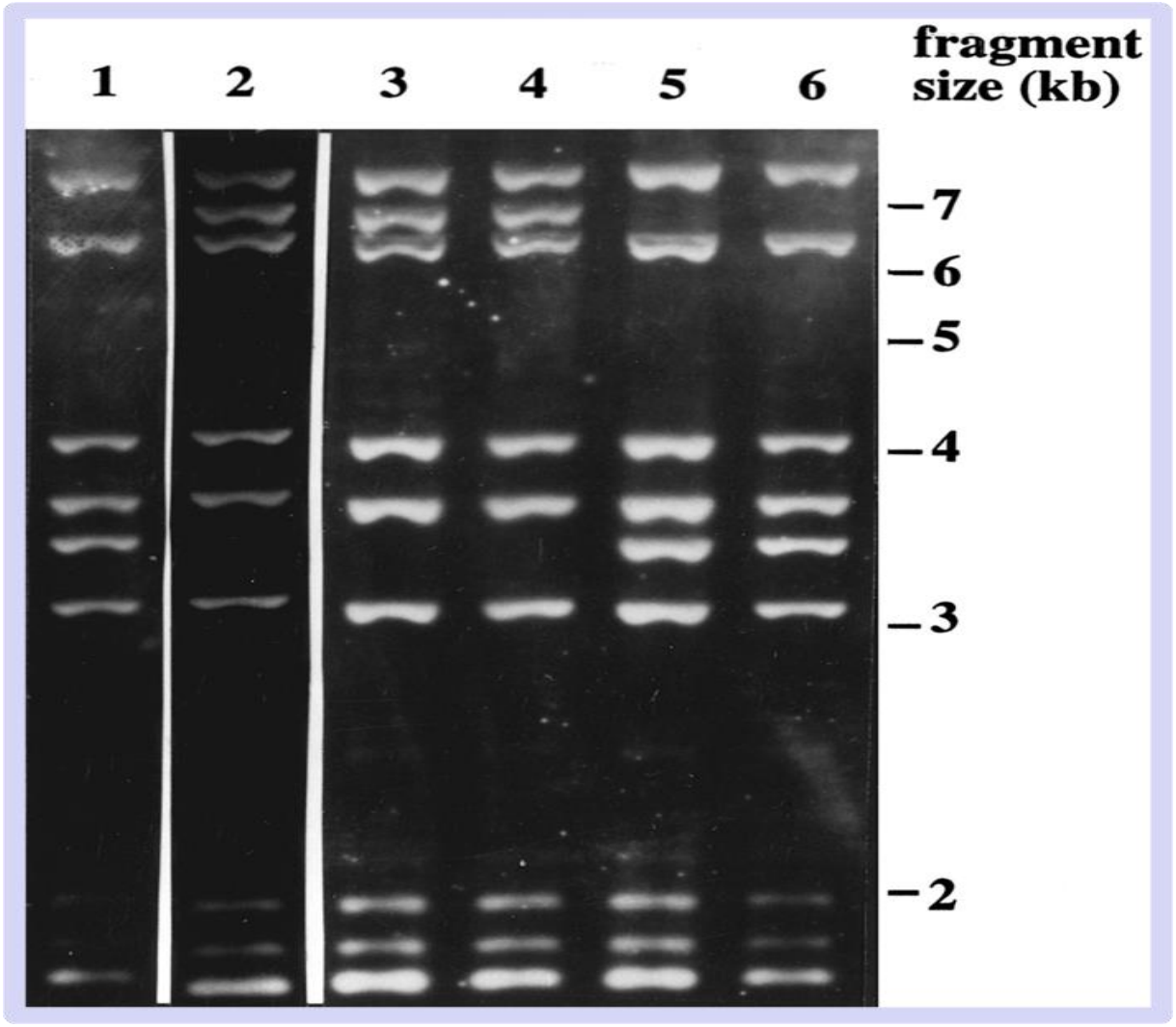
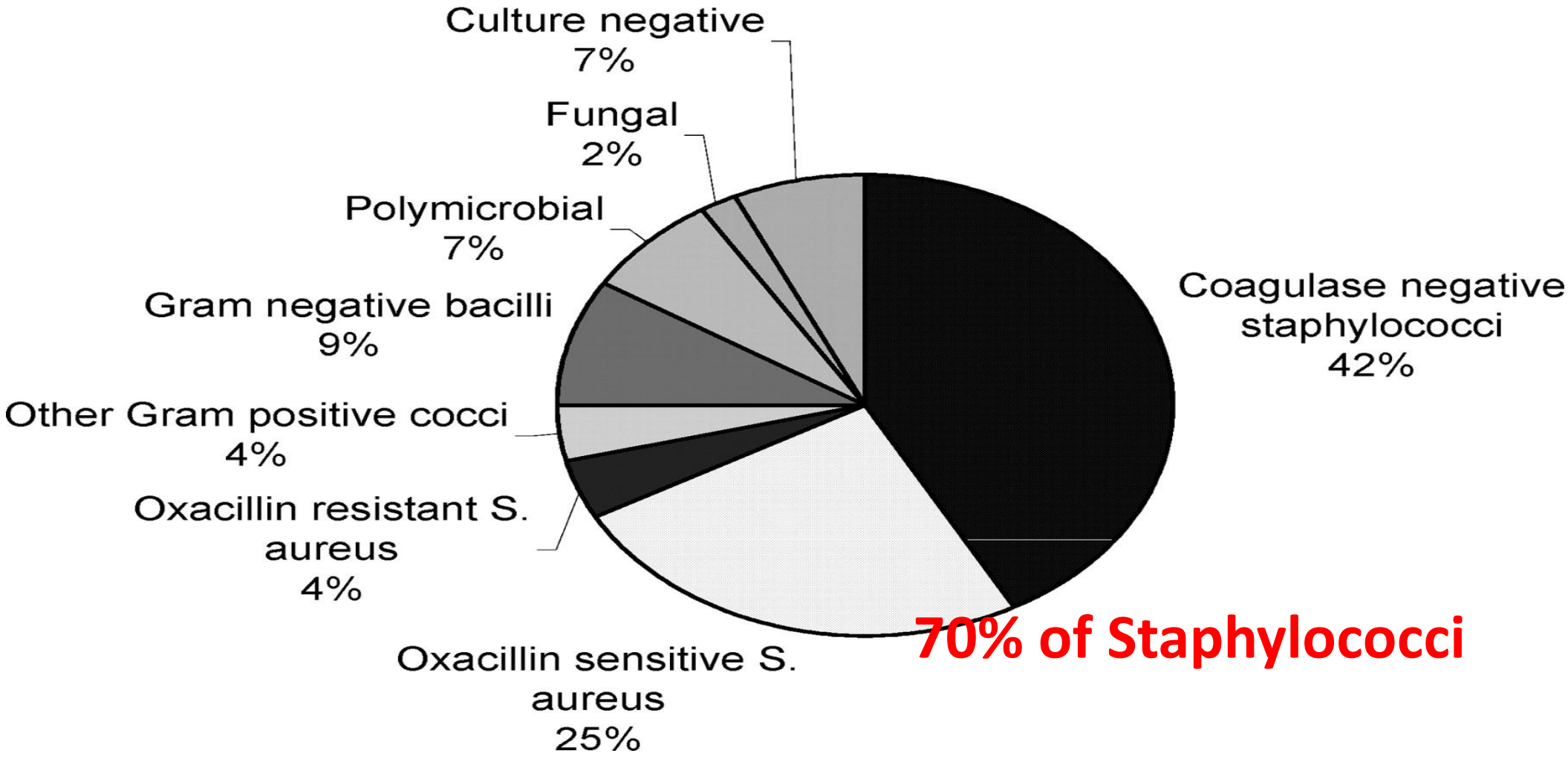


Figure 1. *Hind*III restriction patterns of rDNA from *Staphylococcus schleiferi* isolates.

Lane 1: *S schleiferi* ATCC 43808–type strain;

Lane 2–4, isolates from patient 1 cultured from the generator at implantation (lane 2), blood culture (lane 3), and generator at the time of complication (lane 4);

Bacterial Species involved in CIED infections
Microbiology of PM/ICD infections (n=189)

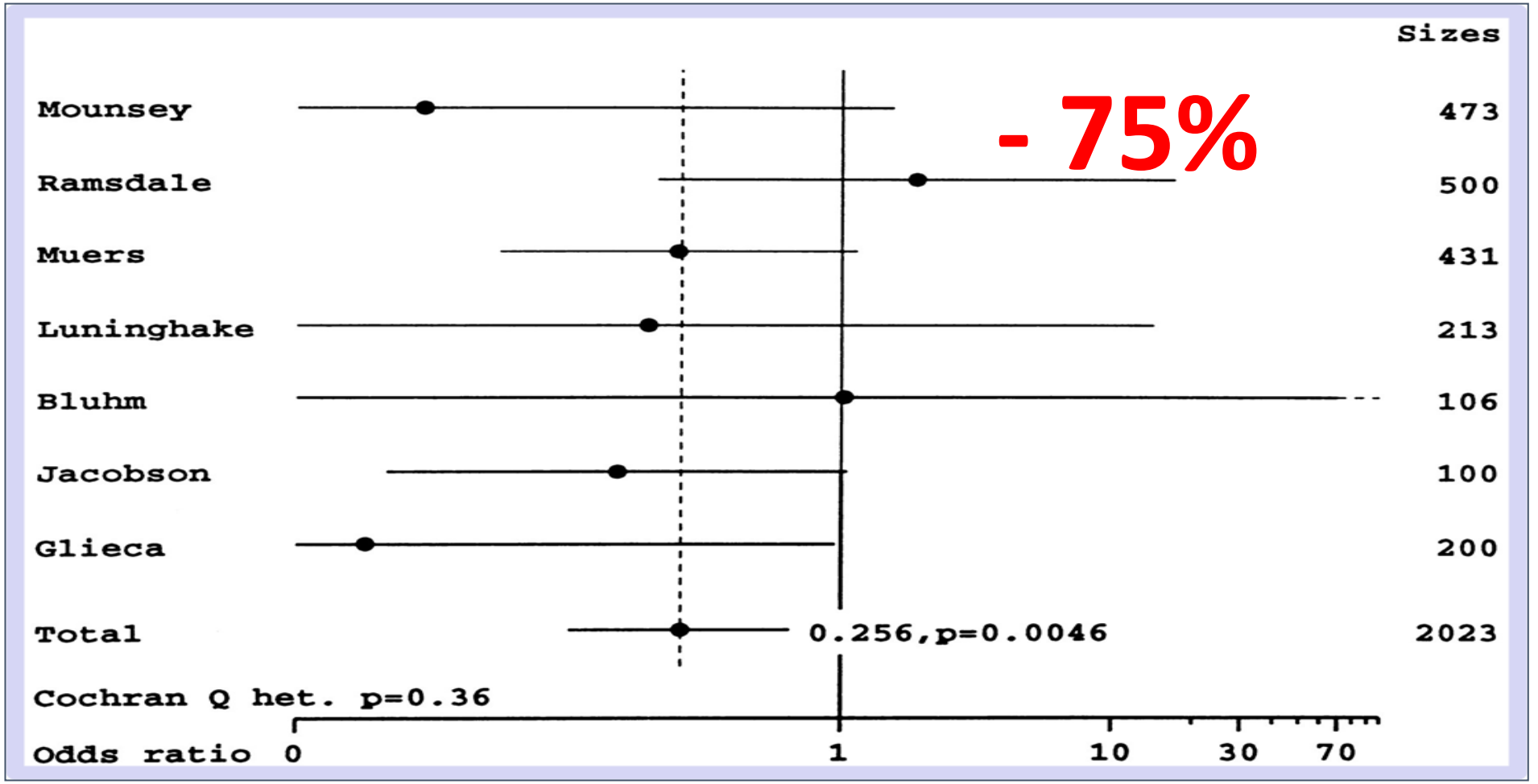


70% of Staphylococci

Baddour, L. M. et al. Circulation 2010;121:458-477

American Heart Association
Learn and Live

CIDE Prevention: Antibiotic prophylaxis efficacy for permanent pacemaker implantation



Da Costa A. et al. Circulation 1998; 97: 1796-1801

CIDE Prevention: Antibiotic prophylaxis efficacy for permanent pacemaker implantation

Variables	Total n=649	Group I (Cefazolin) n=314	Group II (Placebo) n=335	*P*
Age, M±SD, years	64±15	64.1±15.9	64.3±14.8	0.831
Gender M, n/%	303/46	140/45	163/49	0.290
LVEF, %, M±SD	57±26	57±15	56±33	0.826
Diabetes, n/%	101/15	44/14.0	57/17	0.292
pulmonary disease, n/%	10/1.5	5/1.6	5/1.5	0.53
Corticosteroids use, n/%	6/0.9	3/0.9	3/0.9	1.000
Anticoagulant use, n/%	51/7.8	15/4.7	36/10.7	0.005
Temporary PM, n/%	88/13.5	38/12.1	50/14.9	0.294
Implants/replacements, n	303/346	140/174	163/172	0.299
PM/CRT/ICD, n	591/8/50	287/2/25	304/6/25	0.439
Duration of procedure,	70±35	68±27	73±41	0.094
Infections n/%	**13/2%**	**2/0.64%**	**11/3.3%**	**0.016**

Efficacy of Antibiotic Prophylaxis Before the Implantation of Pacemakers and Cardioverter-Defibrillators. Prospective, Randomized, study. de Oliveira J C et al. Circ Arrhythm Electrophysiol 2009;2:29-34

CIDE Prevention: Antibiotic prophylaxis efficacy for permanent pacemaker implantation

Variables	Noninfected (n=636)	Infected Patients (n=13)	*P*
Age, M±SD, years	64.3±15.3	59.4±15.5	0.251
LVEF, %, M±SD	57.3±26.6	50.2±11.38	0.826
Diabetes, yes/no	97/539	4/9	0.129
Chronic pulmonary disease, yes	9/627	1/12	0.184
Corticosteroids use, yes/no	6/630	0/13	1.000
Anticoagulants use, yes/no	**48/588**	**3/10**	**0.075**
Temporary PM, yes/no	85/551	3/10	0.401
Implants/Replacements, n	**293/343**	**10/3**	**0.027**
PM/CRT/ICD, n	579/8/49	12/0/1	0.902
Duration of Procedures, minutes,	**70.1±34.9**	**89.6±29.4**	**0.009**
Pocket Hematoma, yes/no	**14/622**	**2/11**	**0.038**

Efficacy of Antibiotic Prophylaxis Before the Implantation of Pacemakers and Cardioverter-Defibrillators. Prospective, Randomized, study. de Oliveira J C et al. Circ Arrhythm Electrophysiol 2009;2:29-34

Évolution de la morbi-mortalité après infection

Complication Rates Associated With Pacemaker or Implantable Cardioverter-Defibrillator Generator Replacements and Upgrade Procedures, Results From the REPLACE Registry. Circulation 2010; 122: 1553-1561.

Table 3. Device Characteristics at Enrollment

Characteristic	Cohort 1 (n=1031)	Cohort 2 (n=713)	P*
Existing device type, n (%)			<0.001
Pacemaker, single	90 (8.7)	71 (10.0)	
Pacemaker, dual	425 (41.2)	258 (36.2)	
ICD, single	101 (9.8)	137 (19.2)	
ICD, dual	226 (21.9)	183 (25.7)	
CRT-pacemaker	14 (1.4)	15 (2.1)	
CRT-ICD	175 (17.0)	49 (6.9)	
Existing device location, n (%)			0.75
Prepectoral	918 (89.0)	642 (90.0)	
Subpectoral	94 (9.1)	64 (9.0)	
Abdomen, prerectus	11 (1.1)	4 (0.6)	
Abdomen, subrectus	4 (0.4)	2 (0.3)	
Unknown	4 (0.4)	1 (0.1)	
Prior generator replacement, n (%)	234 (22.7)	183 (25.7)	0.17
Duration of implantation,† mean (±SD), y	6.2 (±2.7)	4.4 (±3.3)	<0.001

*P values compare cohort 1 to cohort 2.
†Duration of implant data is unavailable for 3 cohort 1 patients and 5 cohort 2 patients.

Taux infection
≈ 1.5% à 6 mois

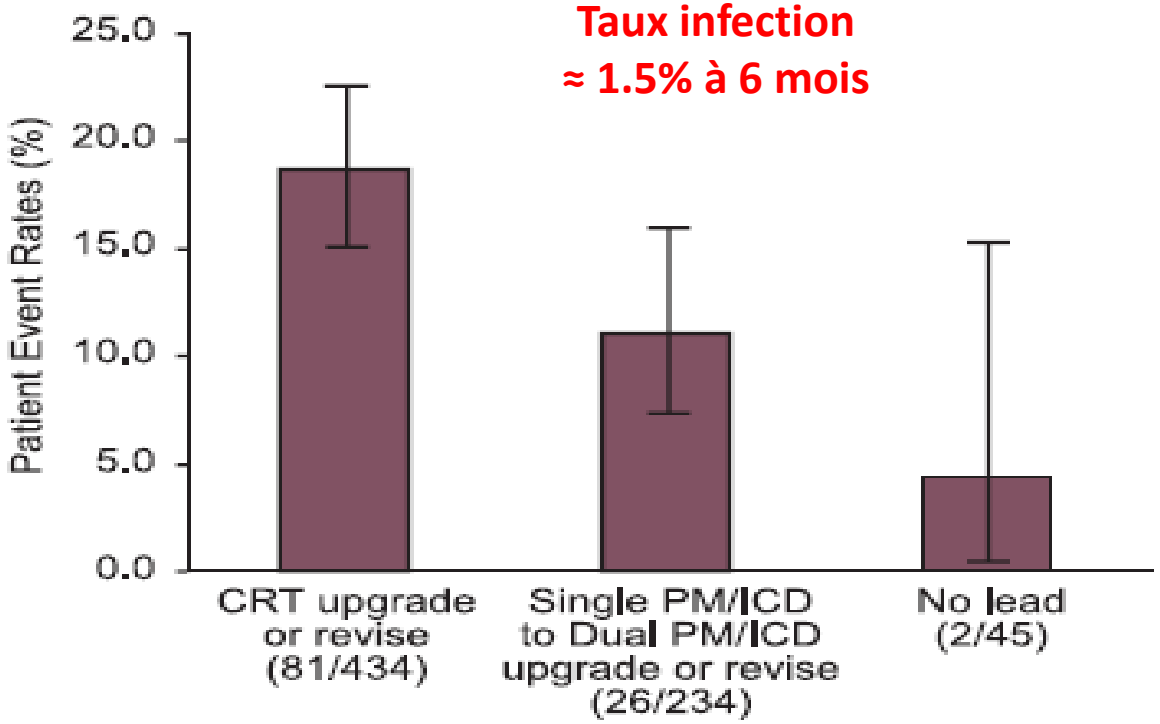


Figure 4. Cohort 2 major complications by lead addition or revision. The bars represent patient complication event rates and 95% confidence intervals. The numbers in parentheses below

Muhammad R. Sohail, MD Arch Intern Med. 2011;171(20):1821-1828

Évolution de la mortalité après infection

- Etude rétrospective sur 200,219 patients du système Medicare admis pour l'implantation, le remplacement ou la reprise d'un dispositif cardiaque

  Mortalité de ~50% à 3 ans chez les patients ayant présenté une infection

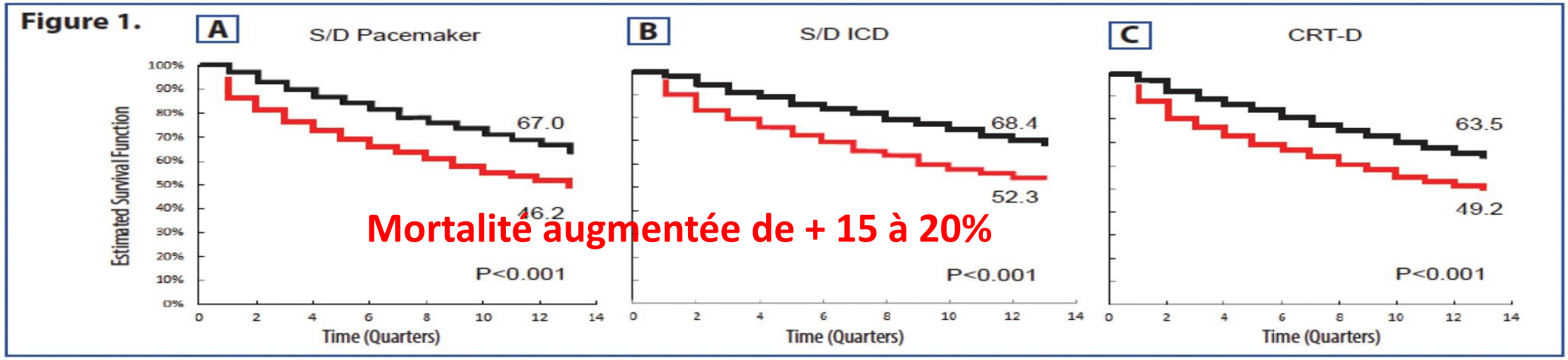


Figure 1. Illustrates Survival** rates following 200, 219 Medicare beneficiary admissions for CIED procedures.
Patients without an infection Patients with an infection

Muhammad R. Sohail, MD Arch Intern Med. 2011;171(20):1821-1828

Antibioprophylaxie IV

- **1 dose de cefazoline [CEFACIDAL] ou de Céfuroxime [ZINNAT]:**
  - Prévention des infections staphylococcique méthi-S
  - 2 g Voie IV ½ heure à 1 heure avant le début de la procédure

- **1 dose de clindamycine [DALACINE IV 600 mg]:**
  - Allergie aux pénicillines
  - Allergie aux céphalosporines

- **1 dose de vancomycine:**
  - Intolérance aux béta-lactamines; 2 heures avant; **15 mg/kg préop dose unique**
  - Suspects d'infections à staphylocoques méti-R [multiples hospitalisations; colonisation avec germes résistants]

Recommandations sur la prévention des infections comparée à la pratique

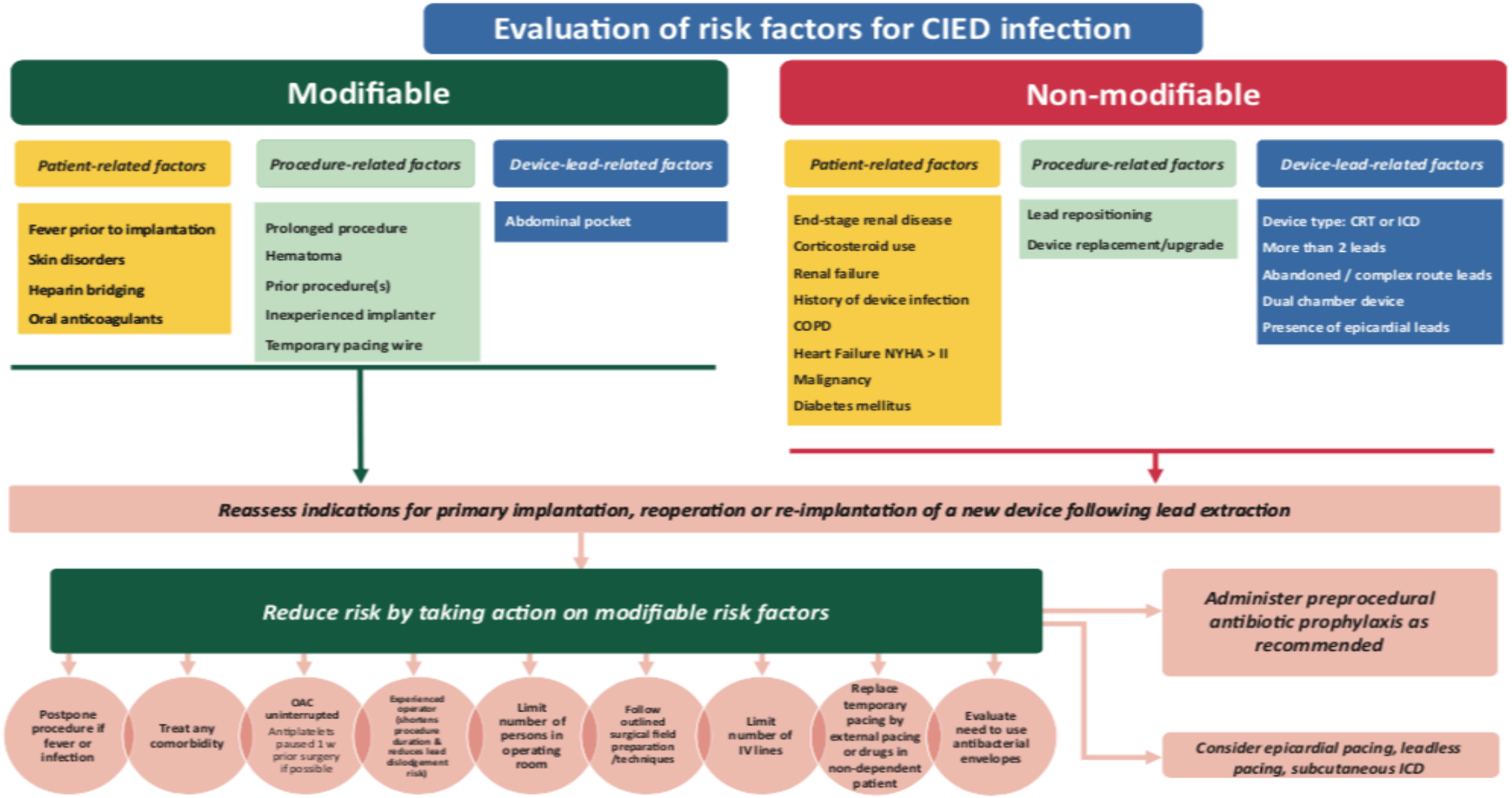


Figure 1 A flowchart indicating how device-related infections can be minimized by targeting modifiable risk factors on various levels. Risk factors ranked in order of strength from top to bottom. CIED, cardiac implantable electronic device; COPD, chronic obstructive pulmonary disease; CRT, cardiac resynchronization therapy; ICD, implantable cardiac defibrillator; NYHA, New York Heart Association; OAC, oral anticoagulation; w, week.

PADIT Study

Étude randomisée en crossover avec 4 groupes de suivi pendant 6 mois avec utilisation:

- soit des doses habituelles d'antibiotiques (céfazoline 1 à 2g IV 60 min avant l'implantation ou vancomycine 1 a 1.5g 120 min avant)
- soit de la **céfazoline** avant la procédure **plus vancomycine**, puis un lavage de poche à la **bacitracine** (bacitracine 50,000 U diluée dan 50 ml serum salé) puis pendant 2 jours de la **cefalexine** per os (500 mg 4 times/day) ou **cephadroxil** (1 g 2X/jour).
- pour les allergies à la pénicilline remplacement par de la **clindamycine** 150 to 300 mg 3X/jour **(Dalacine)**

- **L'objectif primaire était de rapporter les infections chez les patients à haut risque a 1 an.**

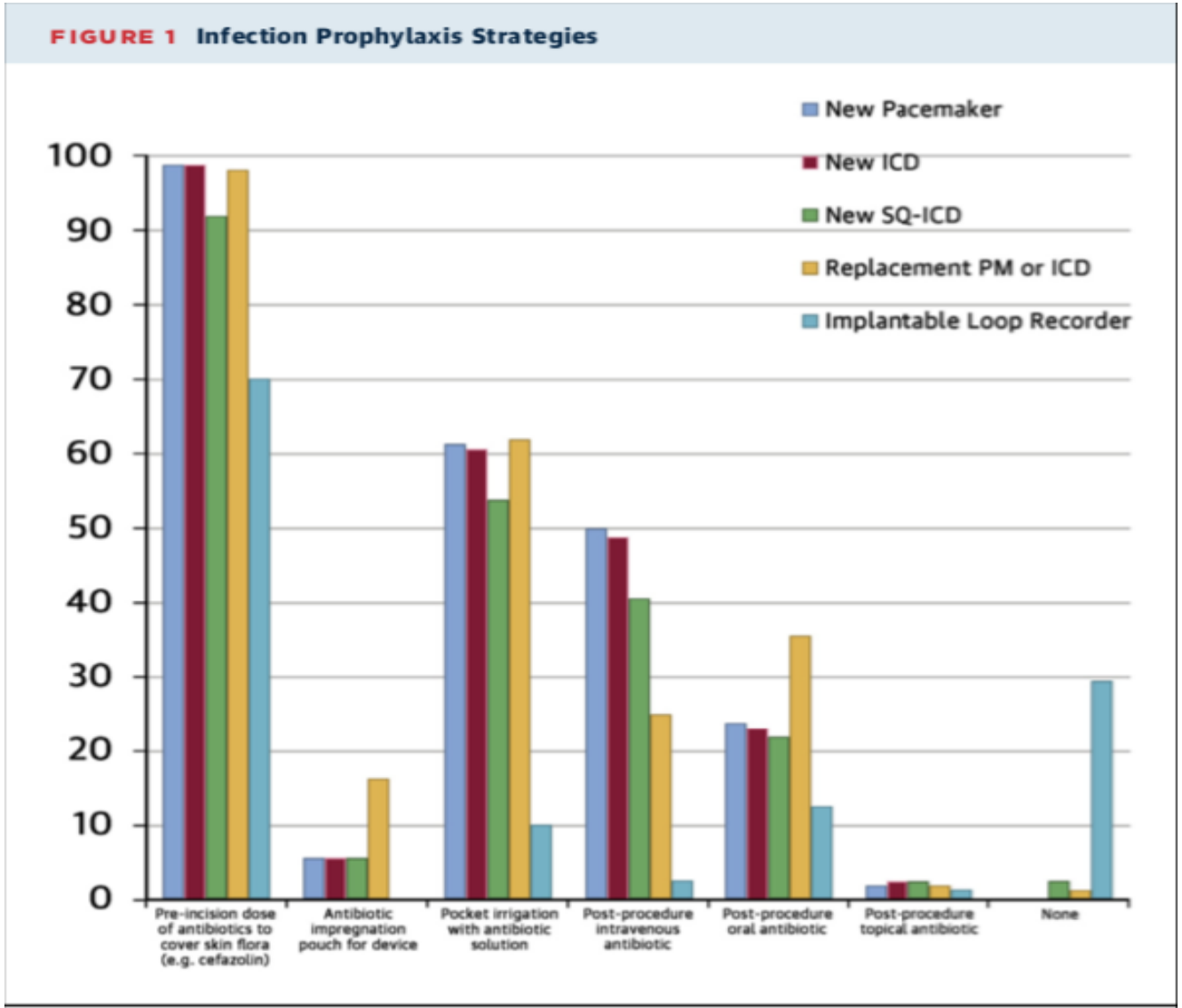
PADIT Study

- **Céfazoline 1 à 2 g IV 60' avant l'implantation ou vancomycine 1 à 1.5 g 120' avant)**
  - ATB de la famille des bétalactamines; **céphalosporine de 1° génération;**
  - Germes sensibles:
    - **aérobies à Gram +** (Staphylococcus méti-S, Streptococcus, Streptococcus pneumoniae);
    - **aérobies à Gram –** (Branhamella catarrhalis, Citrobacter koseri, Escherichia coli, Haemophilus influenzae, Klebsiella, Neisseria gonorrhoeae, Proteus mirabili);
    - **anaérobies :** Clostridium perfringens, Fusobacterium, Peptostreptococcus, Prevotella, Propionibacterium acnes, Veillonella.
- **Céfalexine (CEFACET) ou Cefadroxil:**
  - ATB de la famille des bétalactamines; **céphalosporine de 1° génération;**
  - Germes sensibles :
    - **aérobies à Gram +** (Corynebacterium diphtheriae, Propionibacterium acnes, staphylococcus méti-S, streptococcus, Streptococcus pneumoniae);
    - **aérobies à Gram –** (Branhamella catarrhalis, Citrobacter koseri, Escherichia coli, klebsiella, Neisseria gonorrhoeae, pasteurella); anaérobies : fusobacterium, prevotella.
- **Clindamicine (DALACINE):** pour les allergies à la pénicilline
  - **Macrolides**
  - Germes sensibles:
    - **aérobies à Gram +** (Bacillus cereus, Corynebacterium diphtheriae, Enterococcus faecium, erysipelothrix, staphylococcus méti-S, staphylococcus méti-R, streptococcus B, streptococcus non groupable, Streptococcus pneumoniae, Streptococcus pyogenes);
    - **aérobies à Gram –** (campylobacter); anaérobies (actinomyces, bacteroides, capnocytophaga, Clostridium autres que perfringens et difficile, Clostridium perfringens, eubacterium, fusobacterium, Gardnerella vaginalis, mobiluncus, peptostreptococcus, porphyromonas, prevotella, Propionibacterium acnes, veillonella);
    - **autres** (Chlamydia trachomatis, leptospires, Mycoplasma hominis, Mycoplasma pneumoniae).

Enseignement des registres: la pratique est différente

- Utilisation d'un spectre ATB plus large pour couvrir le risque lié staphylococci résistants à la méthicilline
- Enquête envoyée à 2174 praticiens Heart Rhythm Society
- N=1035

Periprocedural Antibiotic Prophylaxis for Cardiac Implantable. Electrical Device Procedures. Results From a Heart Rhythm Society Survey. JACC electrophysiol 2017

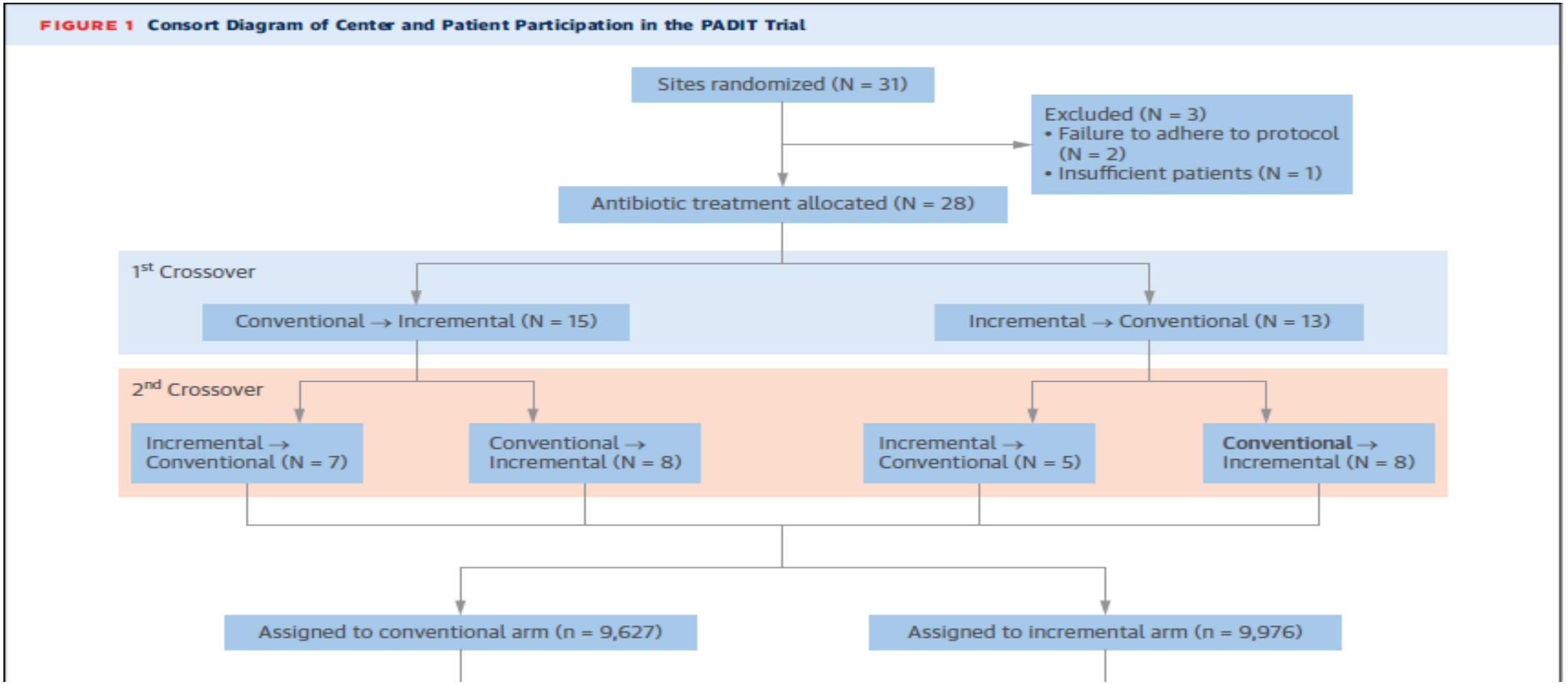


Enseignement de WRAP IT: la pratique est différente

Caractéristiques	Enveloppe (N = 3495)	Contrôle (N = 3488)
Stratégie de gestion de l'infection *		
Antibiotique péri-opératoire	3,402 (98.6%)	3,413 (98.7%)
Antibiotique post-opératoire	**987 (28.6%)**	**1,058 (30.6%)**
Rinçage de la loge ATB	**2,539 (73.6%)**	**2,610 (75.5%)**
Stimulateur cardiaque	723 (20.7%)	709 (20.3%)
CRT-P	133 (3.8%)	157 (4.5%)
DECI - défibrillateur†		
DAI	964 (27.6%)	909 (26.1%)
CRT-D	1,675 (47.9%)	1,713 (49.1%)
Procédure tentée, sans DECI	2 (0.1%)	3 (0.1%)
Pas de procédure tentée	44 (1.3%)	31 (0.9%)

[1] **Tarakji K, Mittal S, Kennergren C, et al. The World-wide Randomized Antibiotic Envelope Infection Prevention Trial (WRAP-IT) to Reduce Cardiac Implantable Electronic Device Infection. Late-breaking abstract presented at ACC 2019; New Orleans, LA.**

Prevention of Arrhythmia Device Infection Trial; The PADIT Trial. Andrew D. Krahn et al. (J Am Coll Cardiol 2018;72:3098–109)



PADIT Study

Country	
Canada	24 (85.7)
the Netherlands	4 (14.3)
Allocation sequence*	
CIIC	7 (25.0)
CICI	8 (28.6)
ICIC	5 (17.9)
ICCI	8 (28.6)
Starting year	
2012	1 (3.6)
2013	20 (71.4)
2014	5 (17.9)
2015	2 (7.1)
Consent for data collection	10 (35.7)

No. of operators	5.5 (3.5-6.5)
Site operator cardiologist vs. surgeon or mixed operator team	14 (50.0)
Implant location	
EP lab only	16 (57.1)
Operating room only	7 (25.0)
Both EP lab and operating room	5 (17.9)
No. of PM generator replacements/yr	86.0 (46.0-112.0)
No. of ICD generator replacements/yr	34.0 (15.0-63.0)
No. of CRT generator replacements/yr	14.5 (5.0-26.0)
No. of pocket/lead revision/system upgrade/yr	48.5 (27.5-80.0)
No. of new CRT PM/defibrillator/yr	35.5 (20.0-53.5)
% Cases with trainee	20.0 (0.0-95.0)
Type of hospital	
Tertiary care	21 (75.0)
Other	7 (25.0)
Antiseptic skin preparation	
Chlorhexidine	26 (92.9)
Iodine	1 (3.6)
Both	1 (3.6)
Skin barrier	14 (50.0)
Intranasal *S. aureus* decolonization	3 (10.7)

PADIT Study

20-25%

75-80%

TABLE 3 Primary and Secondary Outcomes of Patients Who Completed Follow-Up*

		High-Risk Patients				
				Incremental vs. Conventional		
	All (N = 12,826)	Conventional (n = 6,285)	Incremental (n = 6,541)	OR†	95% CI	p Value
Hospitalization due to device infection	143 (1.11)	77 (1.23)	66 (1.01)	0.82	0.59-1.15	0.26
Subtype						
Skin, subcutaneous/pocket infection	124 (0.97)	67 (1.07)	57 (0.87)	0.82	0.57-1.17	0.27
Bloodstream infection	34 (0.27)	19 (0.30)	15 (0.23)	0.76	0.38-1.49	0.42
Endocarditis	37 (0.29)	22 (0.35)	15 (0.23)	0.66	0.34-1.27	0.21
Erosion of skin with device exposure	3 (0.02)	1 (0.02)	2 (0.03)	1.96	0.18-21.70	0.58
Bloodstream and/or endocarditis	49 (0.38)	28 (0.45)	21 (0.32)	0.72	0.41-1.28	0.26
Pocket infection and/or erosion	94 (0.73)	49 (0.78)	45 (0.69)	0.89	0.58-1.37	0.59
Requiring surgical intervention						
Yes	128 (1.00)	66 (1.05)	62 (0.95)	0.90	0.64-1.28	0.57
No	15 (0.12)	11 (0.18)	4 (0.06)	0.35	0.11-1.10	0.07
Antibiotics treatment for infection	103 (0.80)	57 (0.91)	46 (0.70)	0.79	0.52-1.20	0.27
Composite of primary outcome and any antibiotics treatment for infection	239 (1.86)	130 (2.07)	109 (1.67)	0.81	0.62-1.05	0.11
Death	1,119 (8.72)	562 (8.94)	557 (8.52)	0.94	0.80-1.09	0.41
Cardiac death	283 (2.21)	145 (2.31)	138 (2.11)	0.91	0.71-1.16	0.44
Vascular noncardiac death	36 (0.28)	18 (0.29)	18 (0.28)	0.89	0.42-1.86	0.75
Noncardiovascular death	272 (2.12)	131 (2.08)	141 (2.16)	1.01	0.77-1.35	0.92
Others	1 (0.01)	1 (0.02)	0 (0.00)	–	–	–
Unknown	527 (4.11)	267 (4.25)	260 (3.97)	0.95	0.77-1.17	0.64

PADIT Study

TABLE 4 Primary Outcome by Device Type

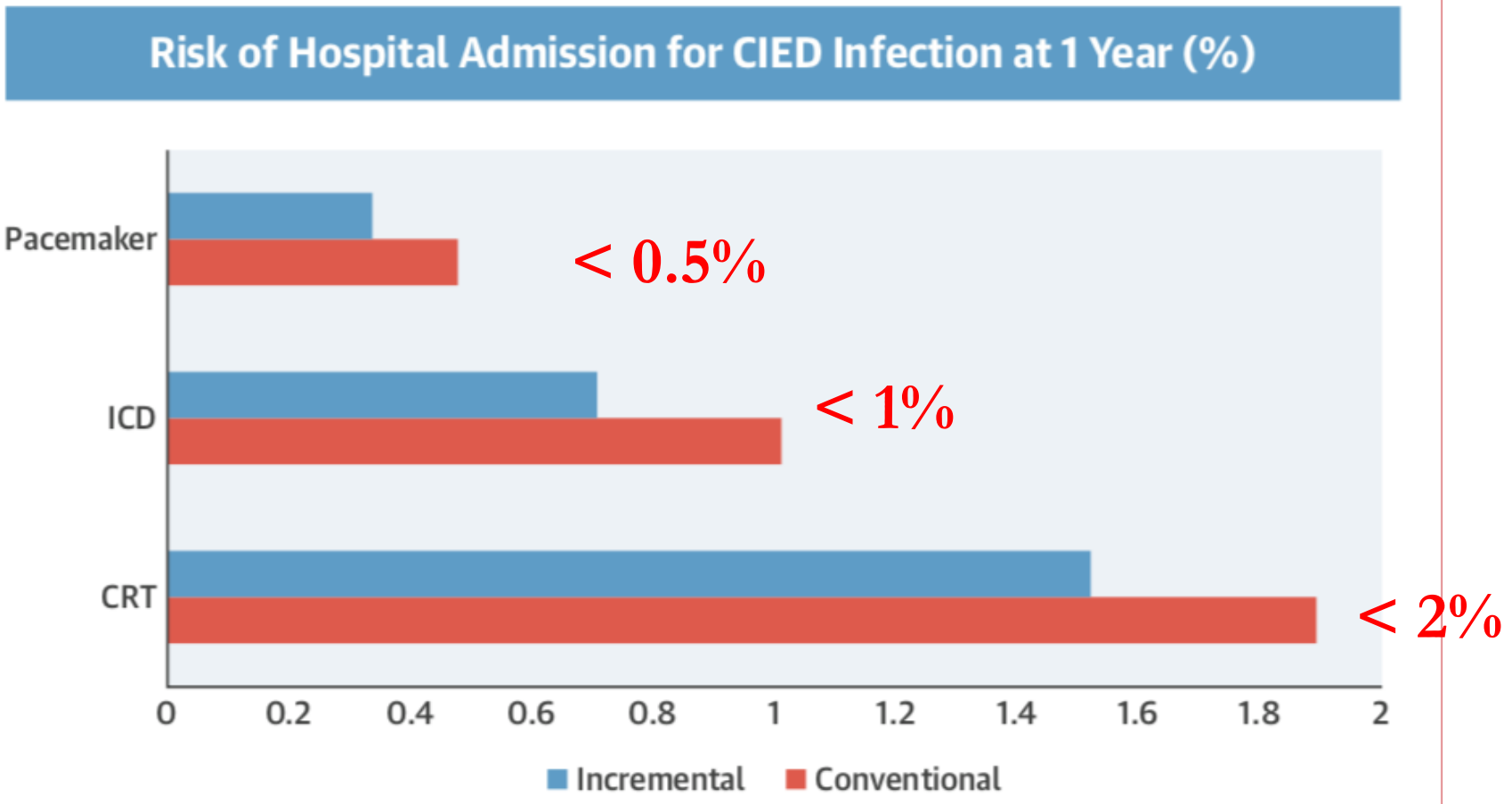
	All	Conventional	Incremental	Incremental vs Conventional OR With 95% CI	p Value for Interaction
Type of procedure					0.92
CRT/revision/upgrade	104/6,103 (1.70)	57/3,021 (1.89)	47/3,082 (1.52)	0.81 (0.54-1.21)	
ICD	35/4,061 (0.86)	20/1,962 (1.02)	15/2,099 (0.71)	0.70 (0.36-1.39)	
Pacemaker	38/9,395 (0.40)	22/4,622 (0.48)	16/4,773 (0.34)	0.72 (0.37-1.38)	

Values are n/N (%) unless otherwise indicated. Infection rates were significantly different between the 3 device types (all pairwise comparisons $p < 0.01$). There was no interaction between device type and treatment effect.

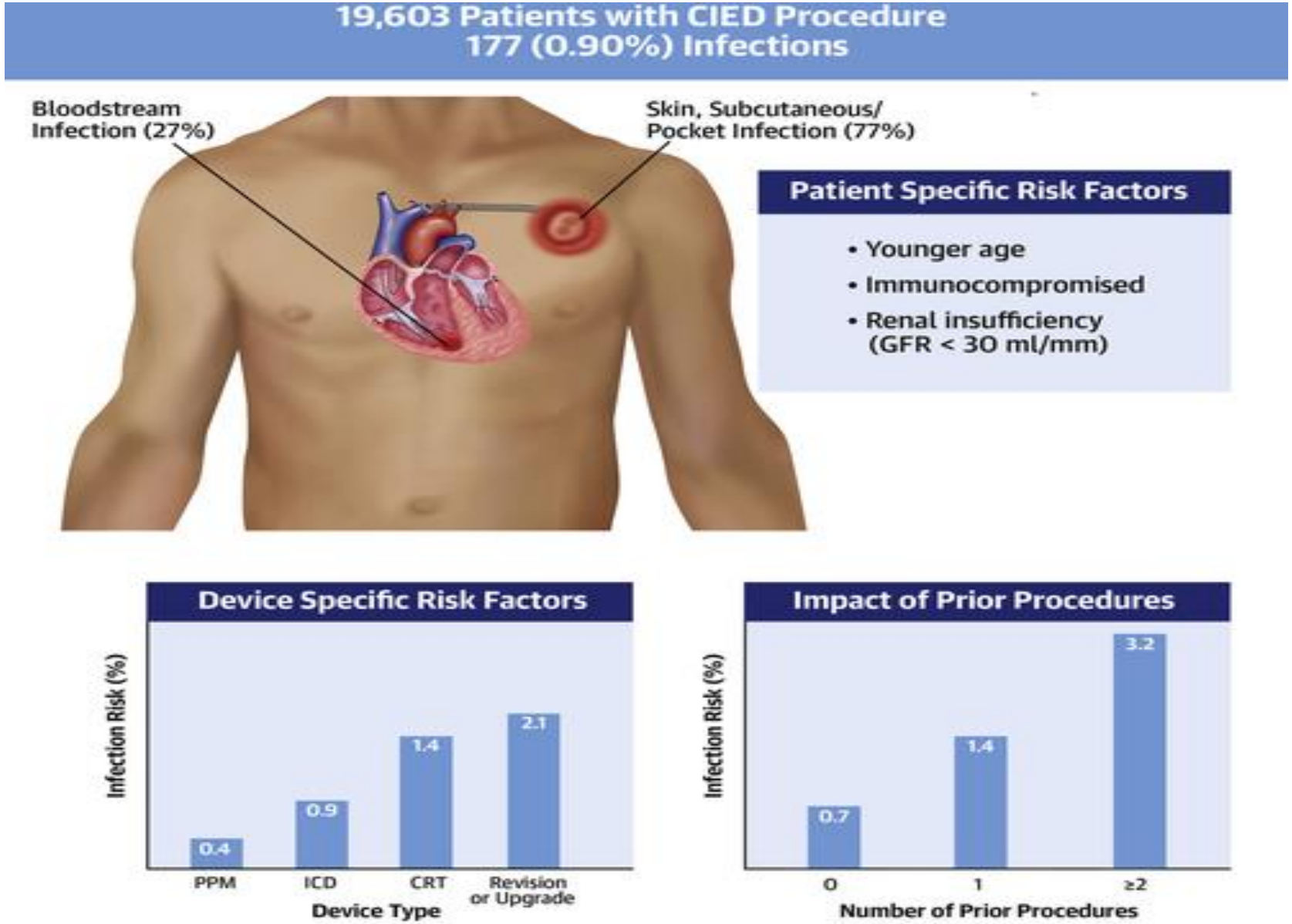
Abbreviations as in Tables 1 and 3.

PADIT Study

CENTRAL ILLUSTRATION Summary of Infection Risks Across Device Platforms in the Prevention of Arrhythmia Device Infection Trial



Krahn, A.D. et al. J Am Coll Cardiol. 2018;72(24):3098-109.



Patients at High Risk for CIED Infection, Volume: 74, Issue: 23, Pages: 2855-2857, DOI: (10.1016/j.jacc.2019.09.058)

Risk Factors for Infections Involving Cardiac Implanted Electronic Devices. Birnie DH et al. J Am Coll Cardiol 2019;74: 2845–54

TABLE 3 Full Prediction Model for Hospitalization due to Device Infection

	OR (95% CI)	β Coefficient	p Value
Age*	—	-0.0274	0.018
1/age^2*	—	-1441.798	0.127
Procedure type (reference: pacemaker)			
ICD	1.77 (1.09-2.87)	0.5717	0.020
CRT	2.73 (1.72-4.31)	1.0026	<0.001
Revision/upgrade†	4.01 (2.62-6.13)	1.3881	<0.001
Renal insufficiency	1.45 (1.00-2.09)	0.3697	0.047
Immunocompromised	2.28 (1.05-4.96)	0.8261	0.037
Number of previous procedure (reference: 0)			
1	1.51 (0.99-2.32)	0.4146	0.058
≥2	3.43 (2.14-5.48)	1.2321	<0.001
Intercept	—	-3.3207	0.001

All variables identified in univariate analysis with $p < 0.25$ were tested for inclusion with a backward elimination approach. Covariates with p values of >0.1 in the multivariable model were individually removed in a stepwise fashion, starting with the one with the highest p value. Finally, to identify other remaining potential confounders, all dropped variables were individually added to the multivariable model and kept in the model if the effect size of any of other predictors changed by >10%. *Age was fractional polynomial transformed. †Revision or upgrade: pocket and/or lead revision and/or system upgrade (i.e., with adding new lead[s]).

CI = confidence interval; OR = odds ratio; other abbreviations as in Table 1.

Score de risque PADIT

TABLE 4 PADIT Score in Clinical Practice

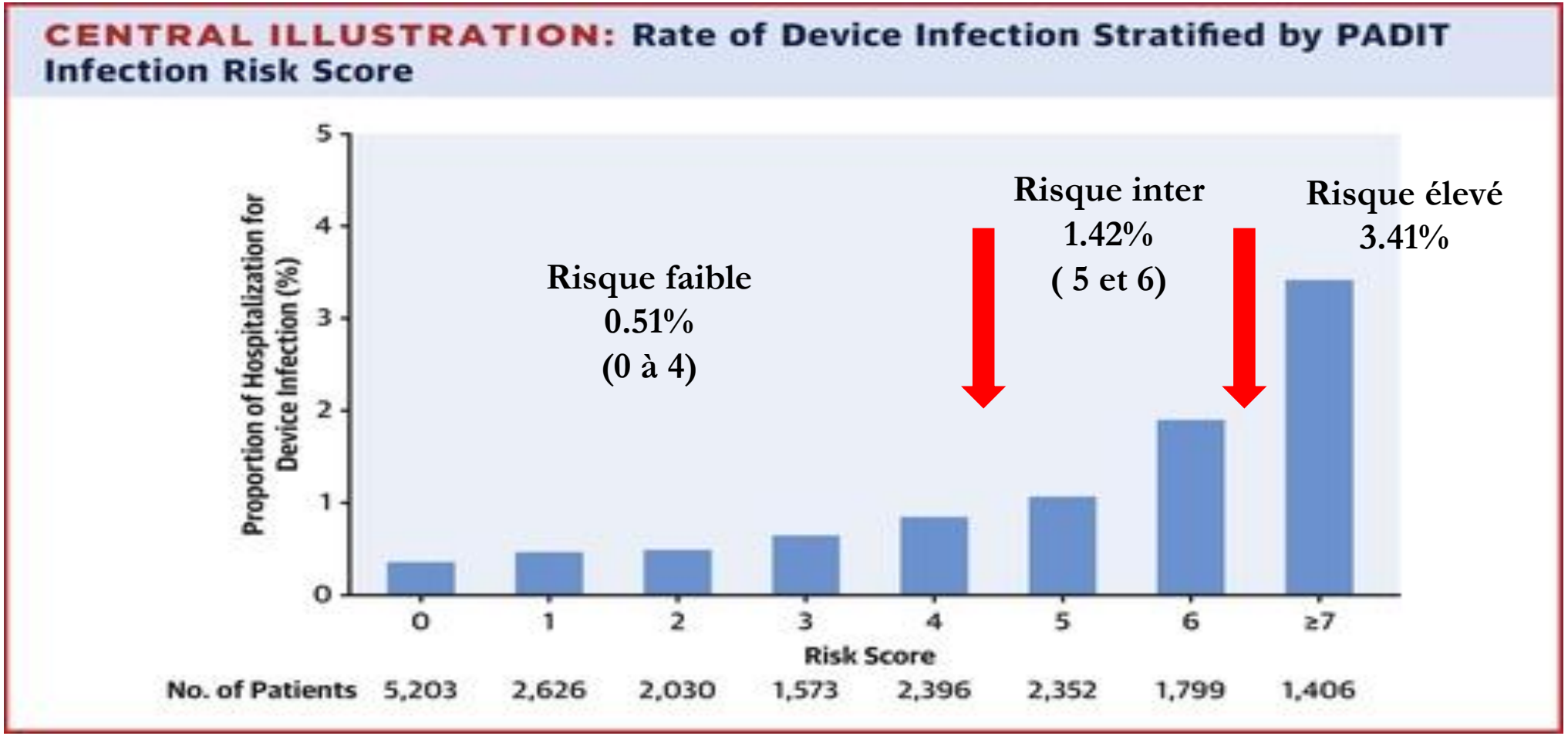
	OR (95% CI)	β Coefficient	p Value	PADIT Risk Score Points
Age, yrs (Ref: 70 yrs)				
<60	1.63 (1.10-2.41)	0.4872	0.015	2
60-69	1.43 (0.99-2.05)	0.3552	0.054	1
Procedure type (Ref: pacemaker)				
Implantable cardioverter defibrillator	1.83 (1.14-2.93)	0.6016	0.013	2
Cardiac resynchronization therapy	2.87 (1.83-4.51)	1.0547	<0.001	4
Revision/upgrade	4.16 (2.74-6.32)	1.4254	<0.001	5
Renal insufficiency	1.48 (1.02-2.13)	0.3890	0.037	1
Immunocompromised	2.24 (1.03-4.86)	0.8051	0.042	3
No. of previous procedures (Ref: none)				
1	1.51 (0.98-2.31)	0.4114	0.059	1
≥2	3.37 (2.11-5.39)	1.2161	<0.001	4

The table shows the points for each of the 5 independent predictors (P: prior procedures; A: age; D: depressed estimated glomerular filtration rate; I: immunocompromised; and T: type of procedure).

Abbreviations as in Tables 2 and 3.

Correction, Volume: 75, Issue: 7, Pages: 840-841, DOI: (10.1016/j.jacc.2020.01.003)

Correction, Volume: 75, Issue: 7, Pages: 840-841, DOI: (10.1016/j.jacc.2020.01.003)



A PADIT risk score ranging from 0 to 15 points classified patients into low (0 to 4), intermediate (5 to 6) and high (7) risk groups with rates of hospitalization for infection of 0.51%, 1.42%, and 3.41%, respectively.

Les enseignements de PADIT

- Une attitude plus agressive au niveau de la prophylaxie antibiotique **n'a pas d'intérêt** comparée à l'injection d'une dose unique de céfazoline IV pour la prévention des infections de dispositifs implantables
- L'étude PADIT devrait permettre d'abandonner ces protocoles de lavage ATB de la loge ou d'ATB post-opératoire qui étaient très largement utilisés en pratique malgré l'absence de preuve
- Le **chiffre de 1% d'infections à 1 an** retrouvé dans l'étude PADIT doit devenir l'objectif à atteindre pour chaque centre implanteur
- Le **score de risque PADIT** devrait être utilisé dans le futur afin de mieux définir les indications ou les modes de stimulation (rôle des PM sans sondes, du DAI sc,…), **mais surtout la place de l'enveloppe TYREX**

Asepsie locale

- Alcool
- Povidone iodée en solution aqueuse à 10%
- Povidone iodée en solution alcoolique à 5%
- Chlorhexidine alcoolique (0,25, 0,5 ou 2%)

Études randomisées asepsie locale

- Chlorhexidine-Alcohol versus Povidone-Iodine for Surgical-Site Antisepsis. **Darouiche RO1, et al. N Engl J Med. 2010 Jan 7; 362 (1): 18-26. (rate of infections in the chlorhexidine-alcohol group compared with the povidone-iodine group 9.5% vs. 16.1%; P=0.004)**

- Skin antisepsis with chlorhexidine–alcohol versus povidone iodine–alcohol, with and without skin scrubbing, for prevention of intravascular-catheter-related infection (CLEAN): an open-label, multicentre, randomised, controlled, two-by-two factorial trial. **Mimoz Olivier et al. Lancet 2015; 396: 2069-77. (rate of catheter related infections in Chlorhexidine-alcohol was lower compared to povidone iodine-alcohol (0·28 vs 1·77 per 1000 catheter-days)**

- A Randomized Trial Comparing Skin Antiseptic Agents at Cesarean Delivery Methodius G. **Tuuli, et al. . N Engl J Med 2016; 374: 647-55. (Rate of infections was 4.0% in the chlorhexidine-alcohol compared to 7.3% in the iodine-alcohol group)**

Preoperative skin antiseptics for prevention of cardiac implantable electronic device infections. A historical-controlled interventional trial comparing aqueous against alcoholic povidone iodine solutions.
Antoine Da Costa et al. Europace J 2015

Table I Group comparison characteristics

	Group I ($n = 648$)	Group II ($n = 678$)	P
Age (year)	73 ± 12	72 ± 13	0.1
Gender (% women)	29%	33%	0.1
Diabetes mellitus	21%	24%	0.2
Dialysis	1.80%	1.50%	0.9
Atrial fibrillation	37%	38%	0.6
Device type			0.1
Single chamber PM	68	72	
Dual-chamber PM	276	278	
CRT-P	39	46	
Single ICD	38	66	
Dual-chamber ICD	49	55	
CRT-D	178	160	
Cardiomyopathy	56%	45%	0.6
LVEF (%)	47 ± 16	49 ± 17	0.2
Primo implantation	439	448	0.6
Generator replacement	209	230	0.6
Follow-up (months)	26 ± 4	26 ± 5	0.5

LVEF, left ventricular ejection fraction; NYHA, New York Heart Association.

- Taux infections: n= 32 (2.4%) 7±7 mois
- 14/648 **(2.2%)** (povidone aqueuse) vs. 18/660 (povidone alcoolisée) **(2.7%)** (p=0.9)
- Prévalence 2.4%
- Incidence de 1%/an

Preoperative skin antiseptics for prevention of cardiac implantable electronic device infections. A historical-controlled interventional trial comparing aqueous against alcoholic povidone iodine solutions.
Antoine Da Costa et al. Europace J 2015

Table 3 Risk factors of CIED infection

Variables	Unadjusted analysis			Multivariate analysis[a]		
	Crude OR	95% CI	P value	Adjusted OR	95% CI	P value
Age	0.99	0.97–1.03	0.87	...	...	...
Gender (ref. category[b]: male)	0.85	0.39–1.86	0.69	...	...	...
Diabetes mellitus	2.20	1.05–4.58	**0.036**	2.10	0.87–5.07	0.10
Dialysis	4.47	0.99–20.08	**0.05**	5.74	0.69–47.94	0.11
Atrial fibrillation	1.80	0.87–3.72	0.11	...	...	...
Dilated cardiomyopathy (ref. category: others or none)	1.73	0.77–3.90	0.19	...	...	...
Ischaemic cardiomyopathy (ref. category: others or none)	0.91	0.40–2.04	0.81	...	...	...
LVEF, mean	0.99	0.98–1.01	0.58	...	...	...
Antithrombotic agent						
Aspirin	0.76	0.34–1.72	0.52	...	...	...
Vitamin K antagonists	1.65	0.81–3.34	0.17	...	...	...
Vitamin K antagonists + aspirin	1.94	0.73–5.12	0.18	...	...	...
Clopidogrel	0.61	0.18–2.02	0.42	...	...	...
Haematoma	71.33	22.98–221.47	**<0.0001**	48.40	13.45–174.25	**<0.0001**
Re-intervention	7.65	3.28–17.81	**<0.0001**	7.16	2.56–19.99	**<0.0001**
Generator replacement	6.35	2.83–14.26	**<0.0001**	1.11	0.31–3.98	0.88
Number of generator replacement, mean	3.28	2.22–4.85	**<0.0001**	3.47	2.22–5.44	**<0.001**

[a]Adjusted for the other variables in the table.
[b]Reference category.

PADIT Study

Country	
Canada	24 (85.7)
the Netherlands	4 (14.3)
Allocation sequence*	
CIIC	7 (25.0)
CICI	8 (28.6)
ICIC	5 (17.9)
ICCI	8 (28.6)
Starting year	
2012	1 (3.6)
2013	20 (71.4)
2014	5 (17.9)
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Operating room only	7 (25.0)
Both EP lab and operating room	5 (17.9)
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No. of ICD generator replacements/yr	34.0 (15.0-63.0)
No. of CRT generator replacements/yr	14.5 (5.0-26.0)
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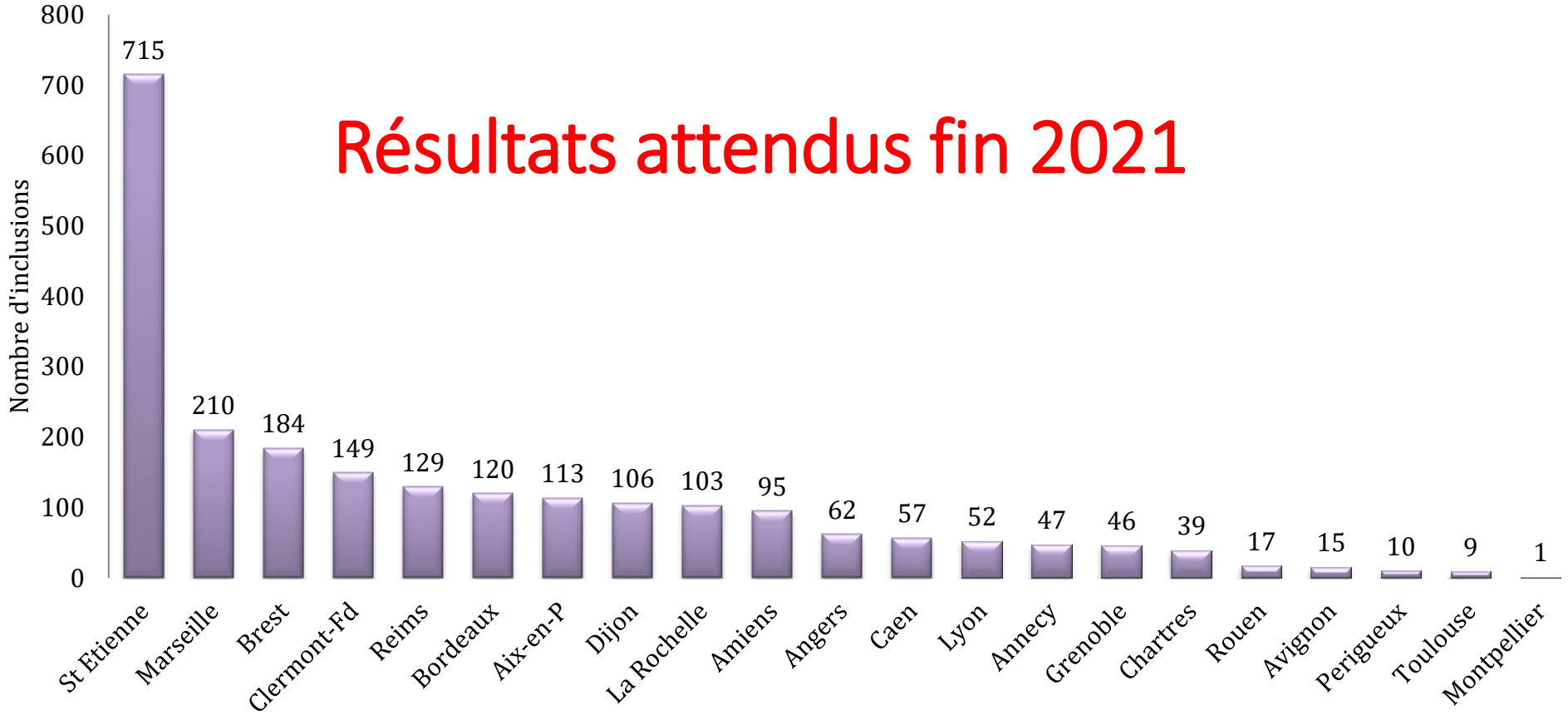
No. of new CRT PM/defibrillator/yr	35.5 (20.0-53.5)
% Cases with trainee	20.0 (0.0-95.0)
Type of hospital	
Tertiary care	21 (75.0)
Other	7 (25.0)
Antiseptic skin preparation	
Chlorhexidine	26 (92.9)
Iodine	1 (3.6)
Both	1 (3.6)
Skin barrier	14 (50.0)
Intranasal *S. aureus* decolonization	3 (10.7)

Newsletter N°27

CHLOVIS
Mars 2019

2276 patients sont inclus dans l'étude CHLOVIS
MERCI à TOUS !!!!

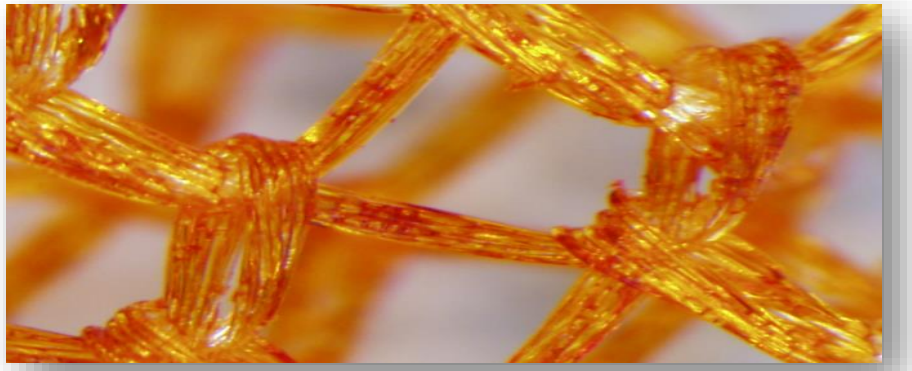


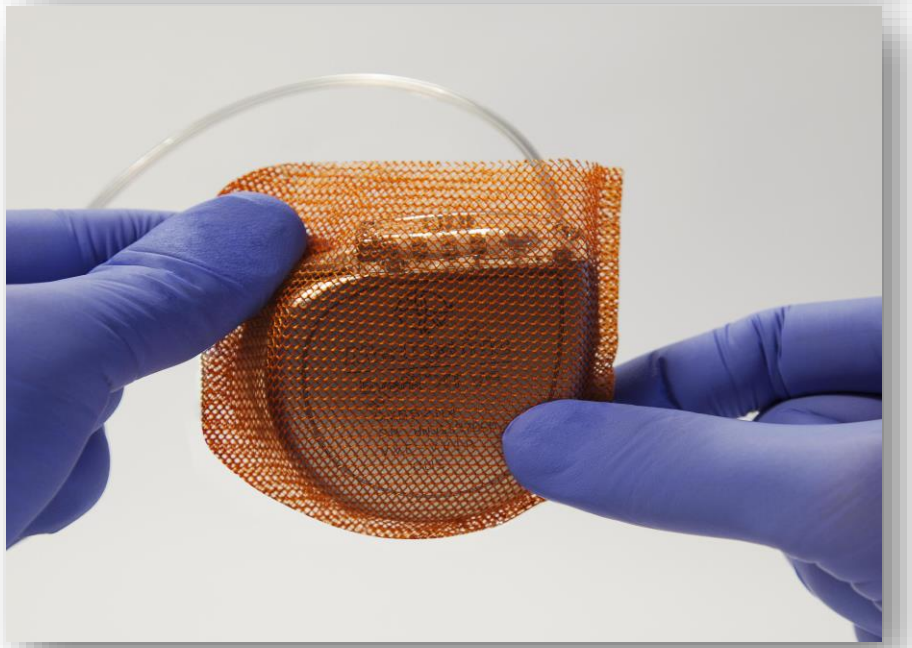
Résultats attendus fin 2021

Investigateurs principaux: Pr A. DA COSTA et Pr J.C. DEHARO

Antiseptique dans la loge: enveloppe antibactérienne TYRX™

- Conçue pour stabiliser le dispositif dans la loge
- L'enveloppe est constituée d'un maillage des filaments résorbable au bout d'environ 9 semaines
- L'action conjointe de deux antibiotiques diffusés localement, **la Rifampicine** et **la Minocycline** permettrait de prévenir la survenue d'infections.
- 2 tailles d'enveloppe sont disponibles : l'une pour les stimulateurs et CRT-P, l'autre pour les DAI et CRT-D



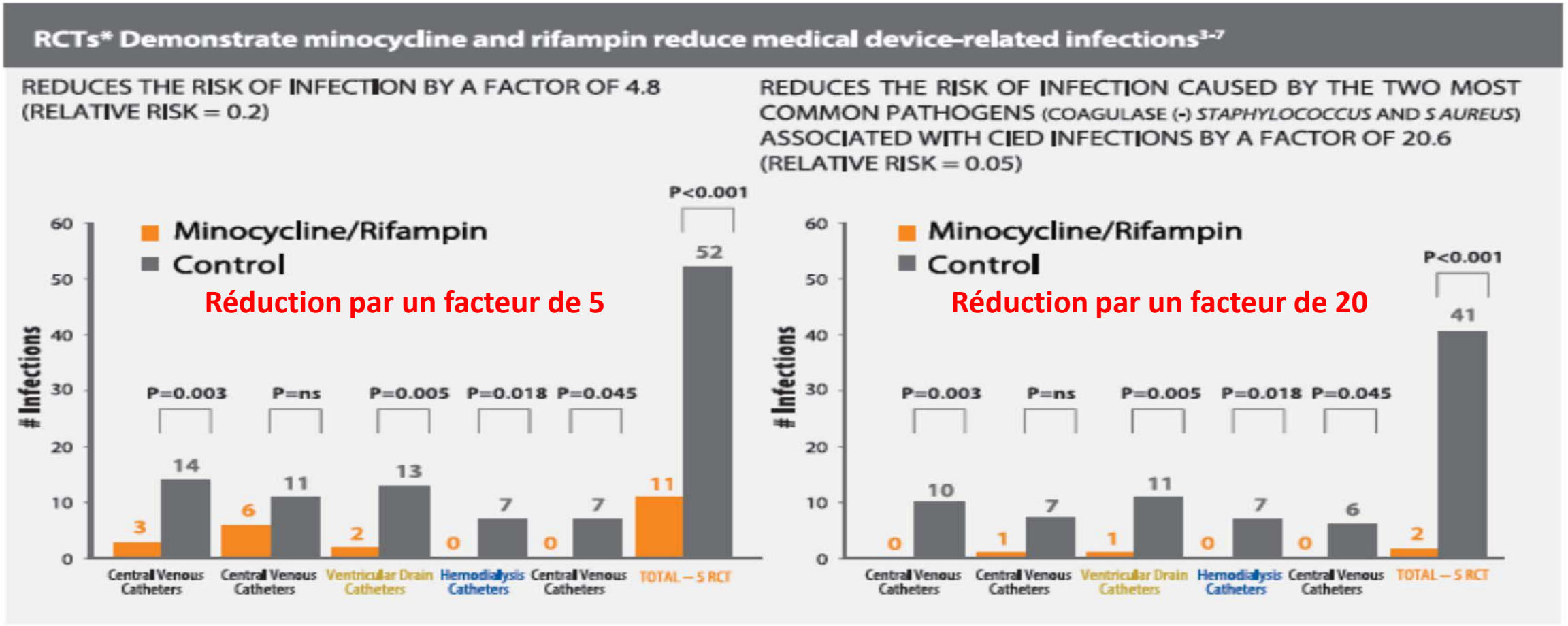


Enveloppe antibactérienne

Germes	cefazoline	vancomycine	TYRX (minocycline et rifamycine)
S. Epidermidis (coagulase -)		+	+
S. Aureus methi S	+	+	+
S. Areus methi R		+	+
E coli	+		+
H influenzae	+		+
M catarrhalis			+
Corynebacterium jeikeium		+	+

Gilbert DN et al. The Sanford Guide to Antimicrobial Therapy 2012, 42th Edition / Zinner SH et al. *J Infect Dis.* 1981; 144 (4): 365-371 / Darouiche RO et al. *Int J Antimicrob Agents.* 1995; 6 (1): 31-36 / Segreti J et al. *Diagn Microbiol Infect Dis* 1989; 12 (3): 253-255

5 études randomisées (RCTs) démontrant que l'association Minocycline/Rifampicine réduit de manière significative les infections (réduction du risque par un facteur de 4.8)



Hanna et al, J Clin Oncol 2004 22(15), 3163
Leon, et al, *Intensive Care Medicine* 2004 30(10), 1891
Zabramski et al, *J Neurosurg* 2003 98(4), 725

Chatzinikoloau et al, *Amer J Med* 2003 115, 352
Raad et al, *Ann Intern Med* 1997 128(4), 267

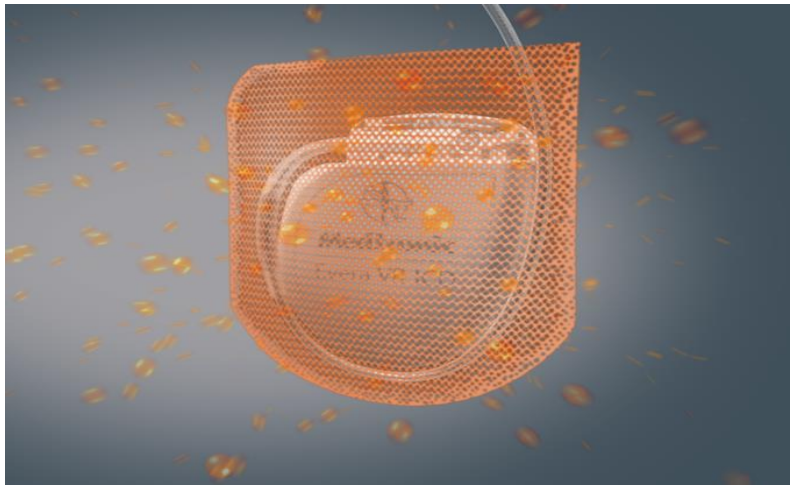
À l’implantation

1. L’enveloppe TYRX doit être placée pendant environ 30 secondes dans du sérum physiologique
2. Une loge légèrement plus grande qu’à l’habitude est nécessaire à son utilisation
3. L’enveloppe TYRX doit ensuite être retournée de manière à ce que les coutures soient tournées vers l’intérieur. Le boitier est ensuite inséré dans l ’enveloppe
4. Puis l’ensemble est placé dans la loge
5. Lors de la fermeture de la loge, il faut veiller à ce que les sutures ne s’insèrent pas dans le maillage du TYRX™

TYRX™ Absorbable Antibacterial Envelope (Large)
Size: 7.4 cm x 8.5 cm
Product # CMRM6133EU (single unit)

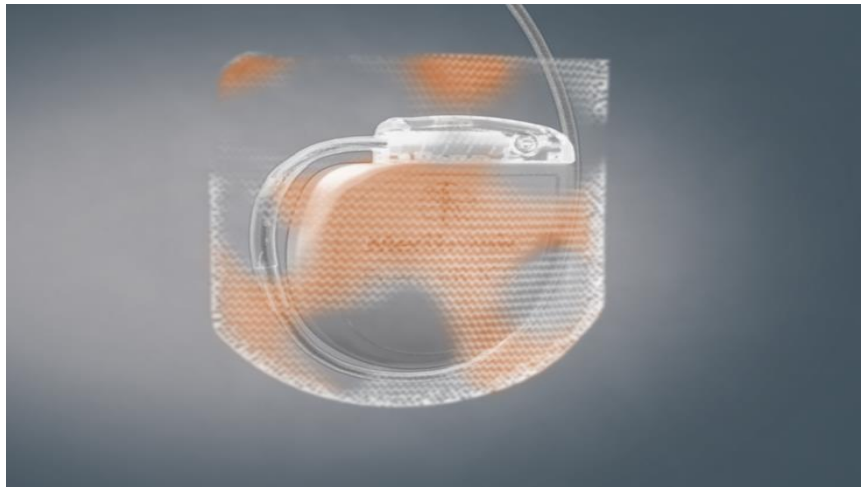
TYRX™ Absorbable Antibacterial Envelope (Medium)
Size: 6.3 cm x 6.9 cm
Product # CMRM6122EU (single unit)

Évolution de l’enveloppe antibactérienne TYRX™



1ère semaine post-implantation :

60 % des antibiotiques sont diffusés dans les premières 24 à 48 heures, le reste dans les 5-6 jours suivants



4 semaines post-implantation :

L’enveloppe se décompose en fragments

9 semaines post implantation :

Résorbtion complète

Quelques remarques

- La Concentration Minimale Inhibitrice (CMI90) est atteinte dans les 2 heures suivant l'implantation et est maintenue pendant 7 jours minimum.

- La dose ne dépasse pas 10% de la dose quotidienne recommandée pour un traitement par voie orale ou intraveineuse. Elle n'est pas détectable dans le sang.

- Le TYRX a été conçu pour être utilisé en complément de l'antibiothérapie prophylactique et non en remplacement.

Implantation success and infection in cardiovascular electronic device using an antibacterial envelope.
Bloom HL et al. Pace. 2011; 34: 133-142

Table III.

Procedures and Rates of Successful CIED Implantation and CIED Infection

Procedure Type	Procedure Device				Total
	PM	ICD/CRT-D	ICD	CRT-D	
Initial implantation					
N/% all procedures	84/13	117/19	48/8	69/11	201/32
Successful implantations/incidence,% [95% CI]	84/100.0 [95.7–100.0]	116/99.1 [96.9–100.0]	48/100.0 [92.6–100.0]	68/98.6 [94.8–100.0]	200/99.5 [98.2–100.0]
Infections/incidence,% [95% CI]	0/0.00 [0.03–4.30]	0/0.00 [0.02–3.10]	0/0.00 [0.05–7.40]	0/0.00 [0.04–5.21]	0/0.00 [0.01–1.82]
Replacement or revision					
N/% all procedures	137/22	286/46	130/21	156/25	423/68
Successful implantations/incidence,% [95% CI]	137/100.0 [97.3–100.0]	284/99.3 [98.1–99.9]	130/100.0 [97.2–100.0]	154/98.7 [96.5–99.8]	421/99.5 [98.7–99.9]
Infections/incidence,% [95% CI]	0/0.00 [0.02–2.66]	3/1.05 [0.38–3.03]	1/0.77 [0.19–4.21]	2/1.28 [0.40–4.55]	3/0.71 [0.26–2.06]
Total					
N/% all procedures	221 (35%)	403 (65%)	178 (29%)	225 (36%)	624 (100)
Successful Implantations/incidence,% [95% CI]	0%	0.74%	0.56%	0.89%	0.48%
Infections/incidence,% [95% CI]					

Abbreviations: PM = pacemaker; ICD = implantable cardioverter-defibrillator; CRT-D = cardiac resynchronization therapy device with defibrillator; N = number of procedures; CI = confidence interval.

50% des patients avec 3 FDR

Limites:

- **suivi très court (2mois)**
- **rétrospectif**

Use of an Antibacterial Envelope is Associated with Reduced Cardiac Implantable Electronic Device Infections in High-Risk Patients.
M J. Kolek et al. Pace. 2011; 34: 133-142

Table III.

Cardiac Implantable Electronic Device Infections among Cases and Controls

	Infections (n, %)	Unadjusted OR	P Value	Adjusted OR	P Value
Entire Cohort					
AIGISRx® Cases (n = 260)	1 (0.4%)	0.13 [0.02–0.95]	0.044	0.09 [0.01–0.73]	0.024
Controls (n = 639)	19 (3%)				
Propensity Score-Matched Cohort					
AIGISRx® Cases (n = 209)	1 (0.5%)	0.11 [0.01–0.85]	0.035	–	–
Controls (n = 209)	9 (4.3%)				

CIED = cardiac implantable electronic device; OR = odds ratio, followed by 95% confidence interval.

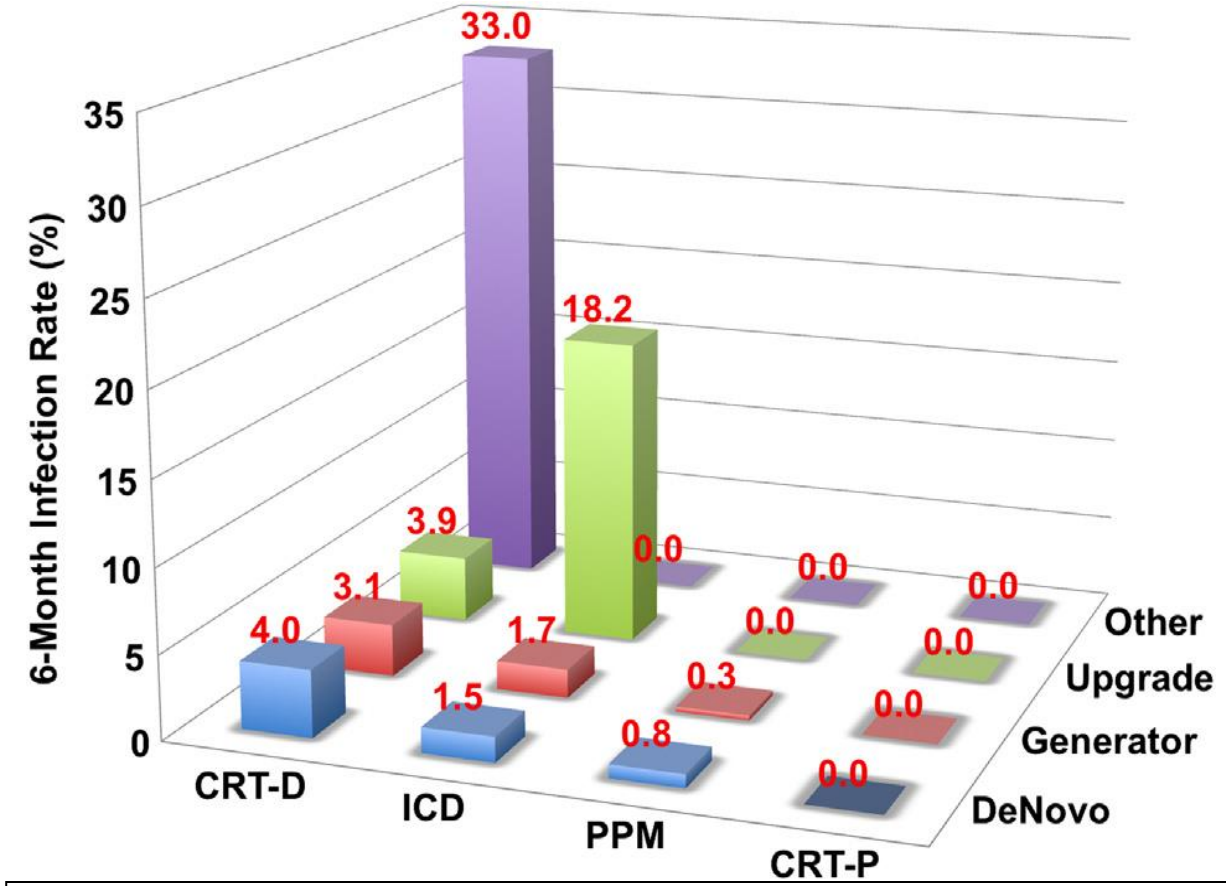
Limites:

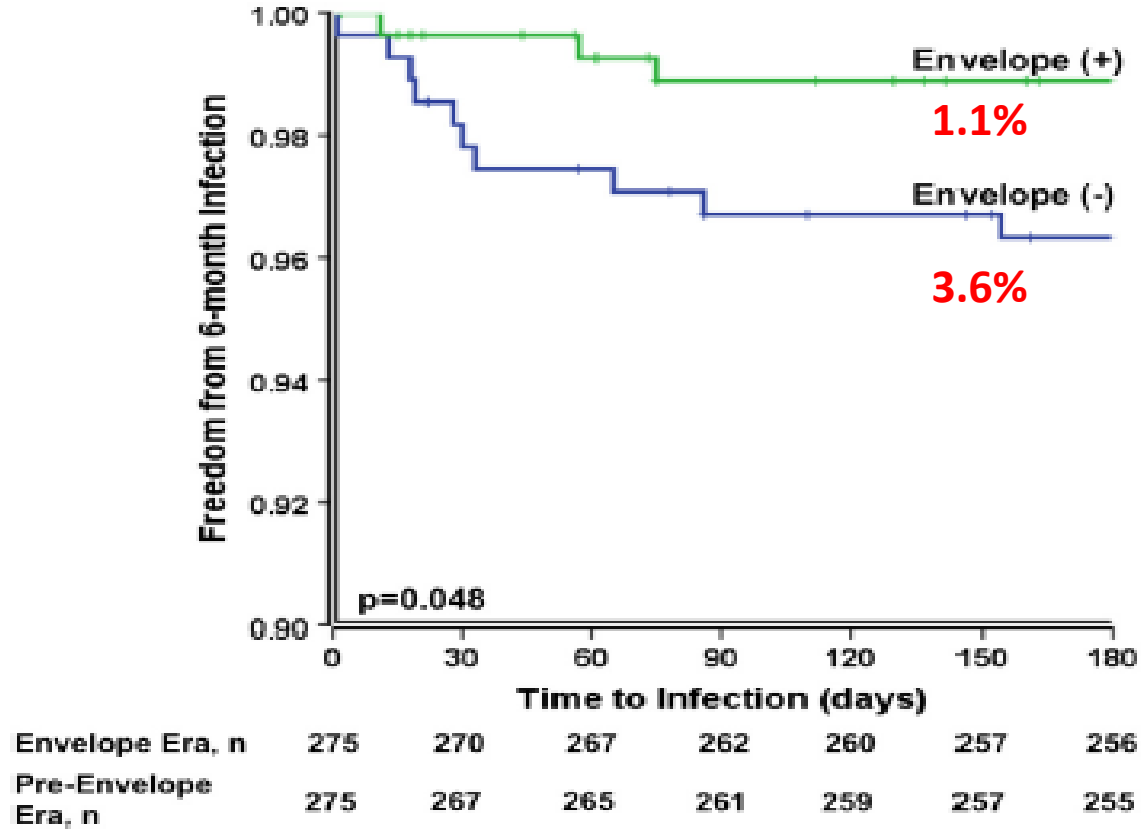
- suivi très court
- rétrospectif

majorité des patients avec 2.8 FDR

Cardiac implantable electronic device infections: Incidence, risk factors, and the effect of the AigisRx antibacterial envelope.

S Mittal Heart Rhythm 2014; 11:595–601



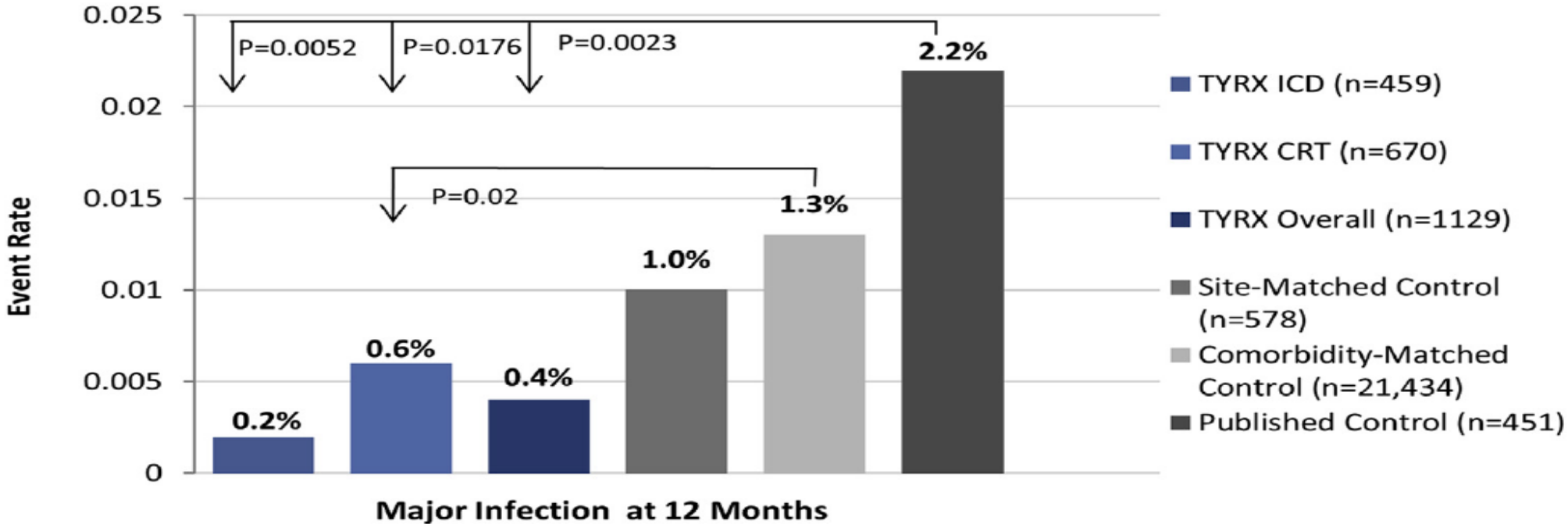


Taux d'infections pour les patients avec PM simple ou double:

- 6 of 987 patients [0.6%]) sans envelope
- 4 of 753 patients [0.5%]) avec envelope

Antibacterial Envelope Is Associated With Low Infection Rates After Implantable Cardioverter-Defibrillator and Cardiac Resynchronization Therapy Device Replacement Results of the Citadel and Centurion Studies Charles A. Henrikson, MD et al. (J Am Coll Cardiol EP 2017; 3: 1158–67)

FIGURE 3 Major Infection Rates



Major infection rates for the trial (Citadel, Centurion, Centurion matched controls, Medicare controls, and prior published controls) are graphed. Major infection rates were significantly lower in TYRX ($p = 0.0023$) compared with the benchmark published control rate. Abbreviations as in Figure 2.

Antibacterial Envelope Is Associated With Low Infection Rates After Implantable Cardioverter-Defibrillator and Cardiac Resynchronization Therapy Device Replacement Results of the Citadel and Centurion Studies Charles A. Henrikson, MD et al. (J Am Coll Cardiol EP 2017; 3: 1158–67)

TABLE 7 Published CIED Infection Rates

First Author (Ref. #)	Year	Study Design	N	Procedure Type	Device	Follow-Up (months)	Infection Rate (%)
Gould et al. (26)	2006	Retrospective	533	Replacement	ICD	2.7 (mean)	1.88
Gould et al. (13)	2008	Retrospective	451	Replacement	ICD	12	2.21
Romeyer-Bouchard et al. (23)	2010	Prospective	303	De novo/ Replacement	CRT-D, CRT-P	12	1.70
Krahn et al. (27)	2011	Prospective	1,081	Replacement	ICD	1.5	1.70
Metais et al. (22)	2011	Prospective	304	De novo	PM, ICD, CRT-D, CRT-P	12	2.30
Uslan et al. (29)	2012	Prospective	1,744	Replacement	PM, ICD, CRT-D, CRT-P	6	1.40

CRT-D = cardiac resynchronization therapy device with defibrillator; CRT-P = cardiac resynchronization therapy device with Pacing function only; PM = pacemaker.

Études cliniques évaluant l'efficacité et la sécurité d'une enveloppe antibactérienne non résorbable

Études	Type	Centres	TYRX	CIED TYRX infections	Contrôle	Suivi (mois)
Command Study 2011 Bloom et al. Pace	rétrospective	10	624	1.05%	2.6%	1.9±2.4
Valley Health Study 2014 Mittal et al. Heart Rhythm	rétrospective	1	275	1.1%	3.6%	6
UPMC Study 2015 Sharrif et al. JCE	rétrospective	1	365	0%	1.9%	12
Vanderbilt 2015 Kolek et al. JCE	rétrospective	1	488	0.3% TYRX 0% TYRX-A	3.1%	3
Citadel/Centurion	**prospective**	**55**	**1129**	**0.44%**	**2.2%**	**12**
WRAP-IT Study	**prospective**	**225**	**7764**	**-**	**-**	**12-36**

Design de l’étude & sélection patient

TYRX™ : L’ÉTUDE WRAP-IT

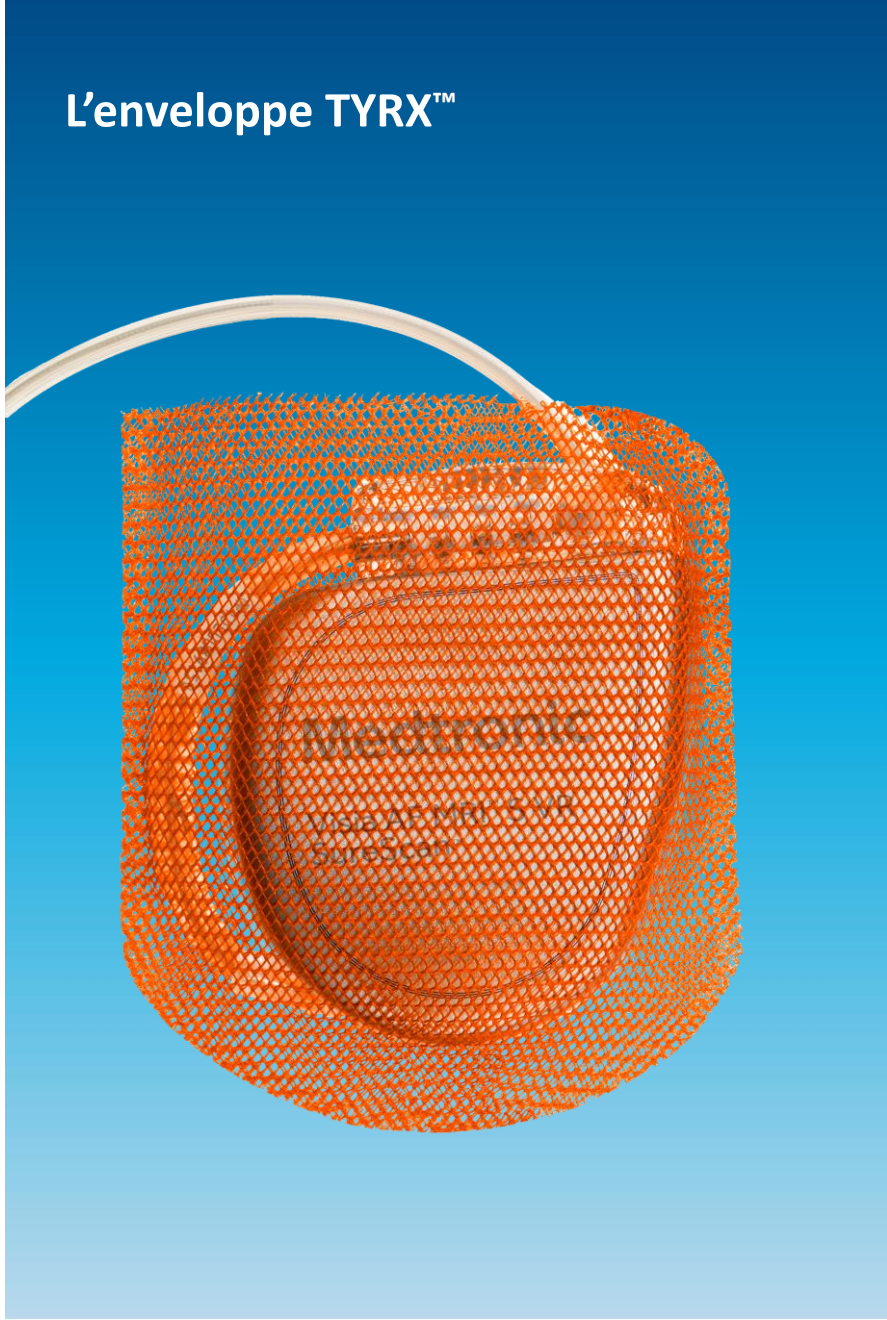
Design de l’étude

- Essai prospectif, randomisé, contrôlé, multicentrique et global
- Randomisation en 1:1 TYRX Enveloppe vs contrôle (pas de TYRX)

Sélection patient

- **Patients à risque accru d'infection de loge du fait d’une :**
  - **Procédure de remplacement, de mise à niveau ou de révision de leur DECI**
  - **Primo-implantation initiale d’un CRT-D**

- **Etaient exclus les patients présentant le risque le plus élevé d'infection systémique lié aux pathologies ou conditions suivantes**
  - **Hémodialyse ou dialyse péritonéale**
  - **Agents immunosuppresseurs (orale chronique ou ≥20mg de prednisone)**
  - **Infection récente (<12 mois) ou existante**



[1] Tarakji KG, et al. *Am Heart J* 2016;180:12-21.

Administration localisée d'antibiotiques synergiques à large spectre

L'ENVELOPPE TYRX™

Activité de la MINOCYCLINE contre les pathogènes[1] infectieux	
BACTERIE à GRAM (+)	**BACTERIE à GRAM (-)**
S aureus ***S pneumoniae***	***E coli*** ***M catarrhalis***
MECANISME D'ACTION Bactériostatique ; inhibe la synthèse des protéines	

Activité de la RIFAMPICINE contre les pathogènes[1] infectieux	
BACTERIE à GRAM (+)	**BACTERIE à GRAM (-)**
S aureus* (incluant SARM)** ***S epidermidis ***C jeikeium***	***H influenzae*** ***M catarrhalis***
MECANISME D'ACTION Bactéricide ; inhibe l'activité de l'ARN polymérase dépendant de l'ADN	

- **Une concentration minimale inhibitrice (CMI) est atteinte dans les 2 heures suivant l'implantation du Tyrx, elle est maintenue ensuite pendant au moins 7 jours.**
- Le Tyrx utilise moins de 5 % de la posologie quotidienne per os recommandée - approche non systémique [1,2]
  - Enveloppe moyenne: 8.0 mg de rifampicine, 5.1 mg de minocycline
  - Enveloppe large: 11.9 mg de rifampicine, 7.6 mg de minocycline

[1] Gilbert DN, et al. *The Sanford Guide to Antimicrobial Therapy*. 39th ed. 2012: Antimicrobial Therapy Inc.; Hyde Park, VT.
[2] Huntingdon Life Sciences Study TR-2013-001.

Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. Khaldoun G. Tarakji, et al . N Engl J Med 2019; 380:1895-905

Characteristic	Envelope (N = 3495)	Control (N = 3488)
Infection Management Strategy*		
Peri-procedure antibiotic	3402 (98.6%)	3413 (98.7%)
Post-procedure antibiotic	987 (28.6%)	1058 (30.6%)
Pocket wash	2539 (73.6%)	2610 (75.5%)
CIED Low Power†		
Pacemaker	723 (20.7%)	709 (20.3%)
CRT-P	133 (3.8%)	157 (4.5%)
CIED High Power†		
ICD	964 (27.6%)	909 (26.1%)
CRT-D	1675 (47.9%)	1713 (49.1%)
Procedure attempted, no CIED	2 (0.1%)	3 (0.1%)
No procedure attempted	44 (1.3%)	31 (0.9%)

Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. Khaldoun G. Tarakji, et al . N Engl J Med 20192019; 380:1895-905

Table 2. Summary of Initial Major CIED Infections within 12 Months.

End Point	Envelope (N=3495)	Control (N=3488)	Total (N=6983)	Hazard Ratio (95% CI)
	number of patients (percent)			
Primary end point: major CIED infection within 12 mo	25 (0.7)	42 (1.2)	67 (1.0)	0.60 (0.36–0.98)*
Type of major CIED infection				
Pocket infection	14 (0.4)	36 (1.0)	50 (0.7)	0.39 (0.21–0.72)
Bacteremia or endocarditis	11 (0.3)	6 (0.2)	17 (0.2)	1.57 (0.61–4.05)

* P=0.04.

The World-wide Randomized Antibiotic Envelope Infection Prevention (WRAP-IT Q1) trial: Long-term follow-up. Mittal S et al. Heart Rhythm J 2020.

Table 2 Major and minor infection types through all follow-up

	Envelope (n = 3371)		Control (n = 3429)			
CIED infection status	Events (patients, %)	KM estimate	Events (patients, %)	KM estimate	Total (N = 6800)	Hazard ratio (95% CI)*
Total CIED infections	**65 (57, 1.7%)**	2.1%	91 (84, 2.4%)	2.8%	156 (141, 2.1%)	0.69 (0.49–0.97)
Major infections within 36 mo†	**38 (32, 0.9%)**	1.3%	56 (51, 1.5%)	1.9%	94 (83, 1.2%)	0.64 (0.41–0.99)
Pocket	18 (17, 0.5%)	0.6%	45 (42, 1.2%)	1.5%	63 (59, 0.9%)	0.41 (0.23–0.72)
Bacteremia/endocarditis	20 (15, 0.4%)	0.7%	11 (10, 0.3%)	0.4%	31 (25, 0.4%)	1.53 (0.69–3.41)
Minor infections within 36 mo	**27 (27, 0.8%)**	0.8%	35 (35, 1.0%)	1.1%	62 (62, 0.9%)	0.79 (0.48–1.30)

CI = confidence interval; CIED = cardiac implantable electronic device.

Epidemiology of cardiac implantable electronic device infections: incidence and risk factors. Hui-Chen Han et al. Europace J 2021

CIED infection risk factors

Device-related

Leads & Generator

More leads	(5.4)
ICD	(1.8-8.5)
CRT	(2.7-28.5)

Additional interventions

Generator replacement	(2.0-3.8)
System upgrade	(3.1-39.6)
Reintervention	(3.1-8.0)

Operative approach

Epicardial
Abdominal device

Patient

Underlying

Younger age	(1.4-1.6)
Male	(1.5)
Renal dysfunction	(1.5-13.4)
Heart disease	(3.8)
COPD	(2.2-9.8)
AF	(3.1)
Immunocompromised	(2.3-13.9)

Transient

Recent fever	(5.8)
Temporary pacing	(2.5)
Anticoagulation	(2.8)

Procedural

Peri-operative

Absence of antibiotics	(2.0-11.5)
Operator inexperience	(2.5)
Procedure duration	(1.03)

Post-operative

Hematoma	(27.2)

Arrêté du 16 avril 2021 portant inscription de l'enveloppe antibactérienne résorbable TYRX de la société MEDTRONIC France au titre III de la liste des produits et prestations remboursables prévue à l'article L. 165-1 du code de la sécurité sociale

CODE	NOMENCLATURE
	Section 16 **Enveloppe antibactérienne résorbable**
	Société MEDTRONIC France (MEDTRONIC)
3412370	Enveloppe antibactérienne résorbable, stimulateur, défibrillateur, MEDTRONIC, TYRX Enveloppe antibactérienne résorbable pour stimulateur et défibrillateur cardiaque implantable TYRX de la société MEDTRONIC France. **DESCRIPTION** L'enveloppe antibactérienne résorbable TYRX est composée d'un substrat en treillis totalement résorbable, d'un revêtement polymère résorbable et de deux antibiotiques (minocycline et la rifampicine). **INDICATIONS :** Prévention du risque d'infection liée à l'implantation de prothèse rythmique cardiaque, chez les patients dans les situations à haut risque d'infection suivantes : – procédure de remplacement, révision ou upgrade de stimulateurs cardiaques ou défibrillateurs cardiaques simple, double ou triple chambre ; – primo-implantation de défibrillateur cardiaque triple chambre (CRT-D). **MODALITÉS DE PRESCRIPTION ET D'UTILISATION** L'utilisation de l'enveloppe antibactérienne résorbable TYRX ne modifie pas les modalités d'utilisation et de prescription des prothèses rythmiques cardiaques implantables. Une seule enveloppe TYRX est nécessaire par intervention. **RÉFÉRENCES PRISES EN CHARGE :** – CMRM6122INT : 6,3 cm x 6,9 cm – CMRM6133INT : 7,4 cm x 8,5 cm Date de fin de prise en charge : 30 avril 2026.

Collège
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Hôpitaux

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