

# ELECTRA

4-5 DÉCEMBRE 2021

HOTEL VILLA M.  
MARSEILLE | FRANCE

1<sup>5</sup>èmes journées françaises  
pratiques de rythmologie  
& de stimulation cardiaque

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VILLA M. - MARSEILLE | FRANCE

**19<sup>èmes</sup> journées françaises  
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# Cardiac implantable electronic device implantation and device-related infection

## Modi *et al.*, 2023 | *Europace*

### Cardiac implantable electronic device implantation and device-related infection

Modi *et al.*, 2023 | *Europace*



Retrospective cohort



Cardiac implantable electronic devices (CIED) are important tools for managing arrhythmias, improving hemodynamics, and preventing sudden cardiac death. Device-related infections (DRI) remain a significant complication of CIED and are associated with major adverse outcomes.

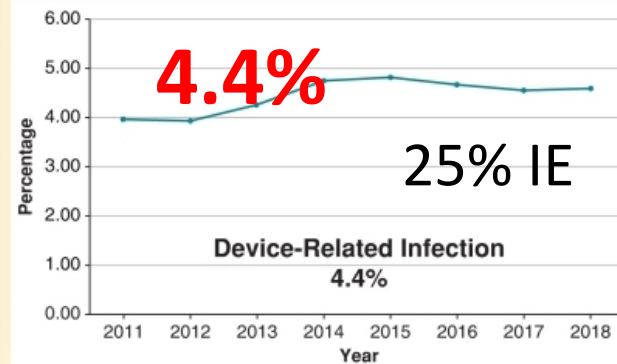
Study setting

We aimed to assess the annual trend in CIED implantations, DRI, and predictors of mortality in patients with DRI.

NIS database 2011–2018



1,604,173 admissions for CIED implantations and 71,007 (4.4%) admissions for DRI



#### Comorbid risk factors for DRI



ESRD coagulopathy  
malnutrition CHF



Timeline

Annual CIED implantations have declined in recent years and are associated with a stable yet high incidence of DRI. These infections cause significant morbidity and mortality among patients and incur a substantial financial burden on the healthcare system.

**Graphical Abstract** CHF, congestive heart failure; CIED, cardiac implantable electronic device; DRI, device-related infections; ...

# Évaluation pré-opératoire

<b>Histoire</b>	
« Hobbies »	Chasse/profession/risques de trauma/crush lead/interférence électromagnétique/permis spéciaux
<b>Médicaments</b>	<b>Anticoagulants/antiplaquettaires</b>
<b>Remplacements/reprises/upgrading/ g/ downgrading</b>	Connecteurs/état des veines
<b>Comorbidités/Score PADIT</b>  <b>PADIT en anglais :</b> <ul style="list-style-type: none"><li>▪ Prior procedure » (interventions déjà subies)</li><li>▪ Age (âge)</li><li>▪ Depressed renal function (fonction rénale affaiblie)</li><li>▪ Immunocompromised (Système immunitaire affaibli)</li><li>▪ Type of procedure (type d'intervention).</li></ul>	<ul style="list-style-type: none"><li>▪ Diabète</li><li>▪ Radiothérapie: état cutané</li><li>▪ ATCD de cancers du sein</li><li>▪ Insuffisants rénaux: dialyse</li><li>▪ État cutané: notamment âge</li><li>▪ ATCD de chirurgie cardiaque</li><li>▪ ATCD d'infections de dispositifs</li><li>▪ Présence de cathéters</li></ul>
<b>Évaluation des préférences du patient</b>	« aspects cosmétiques »
<b>Problèmes allergiques</b>	Antibiotiques; produits iodés; composants silicone; titane; etc...

# Évaluation pré-opératoire




Résultats des tests	
Hématologie + fonction rénale	<b>Coagulation</b> , INR, plaquettes; électrolytes; fonction rénale; <b>CRP</b> ; GB; fibrinogène
ECG	Type trouble conduction (FE); BBG; stimulation VG → choix du côté FA → PM sans sonde
Echocardiographie	LVEF; VCSG si SC dilaté; grade IT++
Radio pulmonaire	Anomalies morphologiques/accès veineux
Doppler veineux/angioscanner	Reprises; upgradings

# Évaluation pré-opératoire

- Meilleur traitement des infections → prévention
- Bénéfice / risque de l'implantation
- Différer une implantation en cas d'infection: ATB; CRP; syndrome inflammatoire inexpliqué
- **1/3 des patients explantés ne nécessitent pas de réimplantation**
- **En cas de haut risque infectieux:**
  - dispositifs sans sonde ou stimulation épicaudique notamment pour les patients avec ATCD d'infections de dispositifs
  - enveloppe Tyrex

# EHRA consensus 2020 / ROME coding

**Table 1** Scientific rationale of recommendations












Consensus statement related to a treatment or procedure	Definitions of consensus statement	Statement class	Scientific evidence coding (SEC)	Ref.
Recommended/indicated or 'should do this'	Scientific evidence that a treatment or procedure is beneficial and effective. Requires at least one randomized trial, or is supported by large observational studies and authors' consensus		R	
May be used or recommended	General agreement and/or scientific evidence favour the usefulness/efficacy of a treatment or procedure. May be supported by randomized trials based on small number of patients or not widely applicable		O	
Should NOT be used or recommended	Scientific evidence or general agreement not to use or recommend a treatment or procedure		E	

This categorization for the consensus document should not be considered as being directly similar to that used for official society guideline recommendations which apply a classification (I-III) and level of evidence (A, B, and C) to recommendations.








The 'ROME' coding was applied for each consensus statement, defining existing scientific evidence.

E, expert opinion; M, meta-analyses; O, observational studies; R, randomized trials.

# EHRA consensus 2020 / ROME coding

Consensus	Classe évaluation	Code scientifique
Confirmer l'indication		E
Différer l'implantation si suspicion d'infection		E
Éviter les SEE ou les voies centrales Enlever les SEE ou les voies centrales		O, M
<b>Mesures pour éviter les hématomes</b>		R
<b>Utilisations des HBPM</b>		R, M, O
Bloc opératoire ou équivalent		E
Procédure supervisées par un opérateur expérimenté		O
<b>Décolonisation du staph aureus (nasale)</b>		E
<b>Douche bétadinée ou hibiscrub</b>		E
Rasage avec rasoir électrique		O
Antibioprophylaxis IV 1 H avant avec la céfazoline ou flucloxacilline ou 90-120 min avant avec la vancomycine		R, M

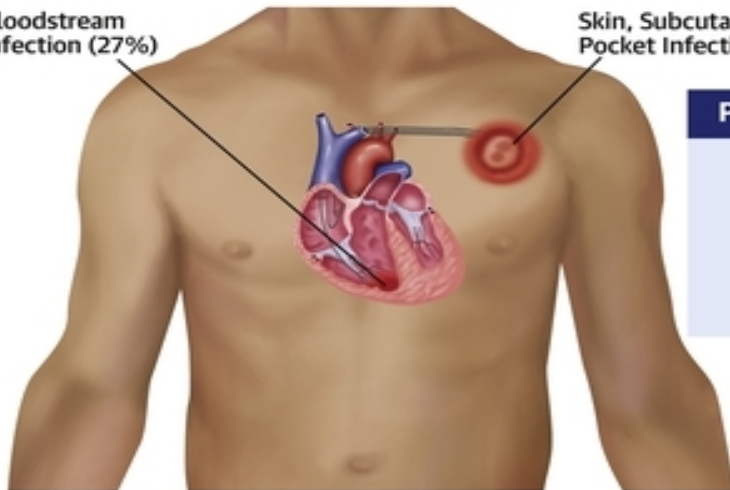
# EHRA consensus 2020 / ROME coding

Consensus	Classe évaluation	Code scientifique
Préparation chirurgicale avec chlorhexidine alcoolique supérieure à la povidone iodée		R
Séchage de la préparation antiseptique locale		E
Champs opératoires adhésifs		E
		
Mesures hémostatiques et de fermetures		E
Enveloppes ATB dans les situations à haut risque		R
Si opérateur réalise la préparation et le drappage: <ul style="list-style-type: none"><li>- changement de gants</li><li>- re-lavage</li><li>- enlever les gants doublés avant incision</li></ul>		E
<b>Instiller des ATB ou des antiseptiques dans la loge</b>		R, E
<b>Utilisation de fils tissés ou tressés pour la fermeture finale de la peau</b>		E

# Case CIED endocarditis....What's new in prevention ? PADIT SCORE

19,603 Patients with CIED Procedure  
177 (0.90%) Infections

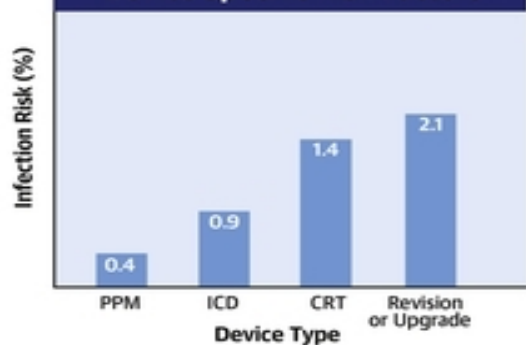
Bloodstream Infection (27%)  
Skin, Subcutaneous/  
Pocket Infection (77%)



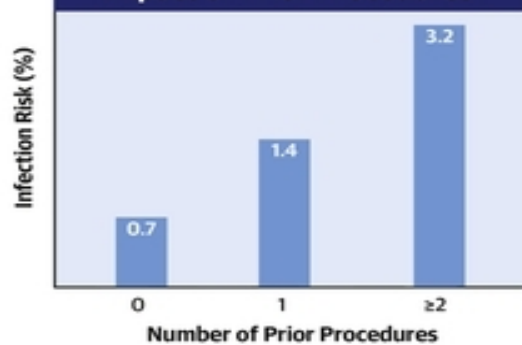
### Patient Specific Risk Factors

- Younger age
- Immunocompromised
- Renal insufficiency (GFR < 30 ml/mm)

### Device Specific Risk Factors



### Impact of Prior Procedures



**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 <sup>2*</sup>	–	-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/upgradet	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](#).

Patients at High Risk for CIED Infection, Volume: 74, Issue: 23, Pages: 2855-2857, DOI:

10.1016/j.jacc.2019.09.058  
2025 Madrid of Cardiology

# Score de risque PADIT

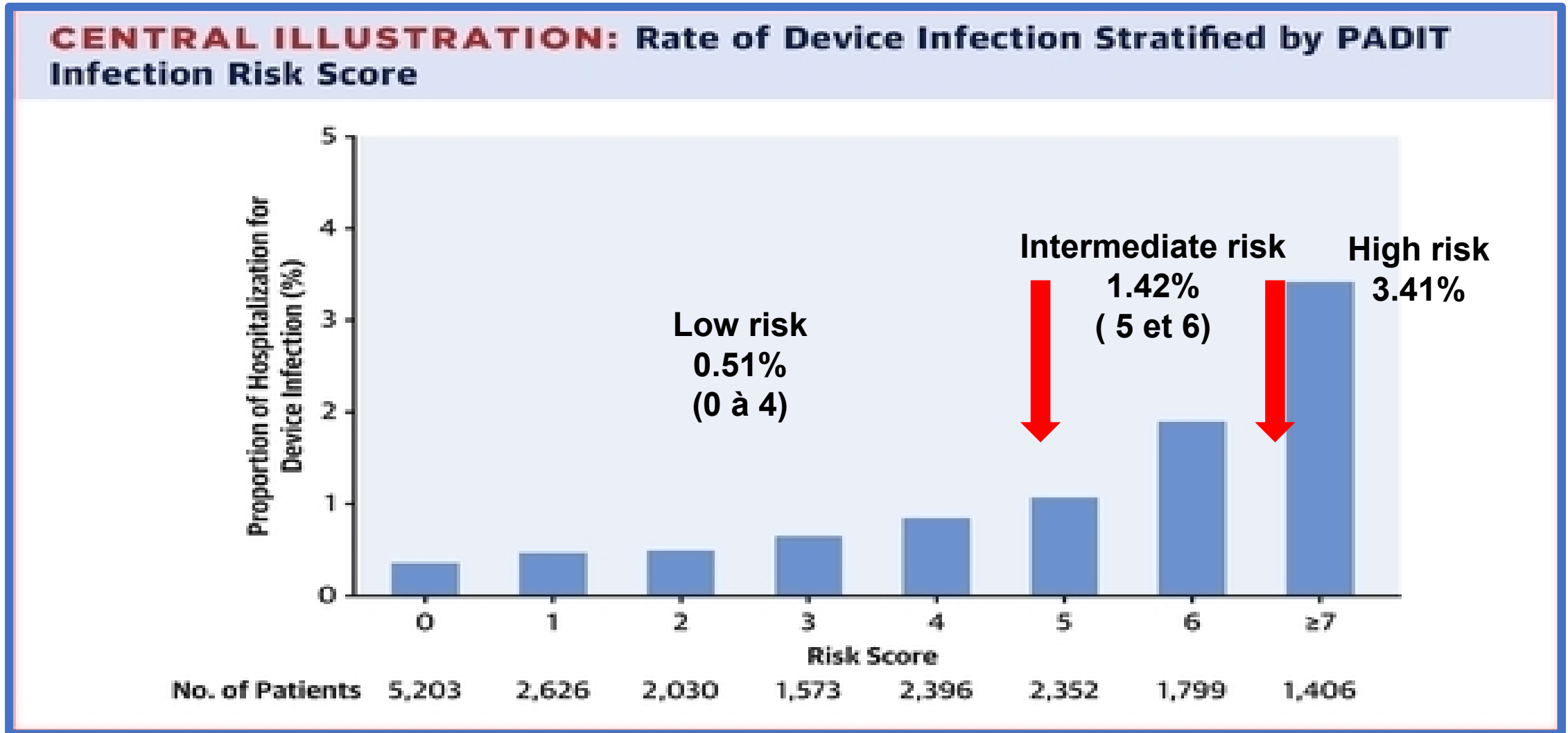
**TABLE 4 PADIT Score in Clinical Practice**

	OR (95% CI)	$\beta$ 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
$\geq 2$	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](#).

# PADIT Score



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

# Antibioprophylaxie IV ce qui doit se faire

- **1 dose de cefazoline [CEFACIDAL] ou de Céfuroxime [ZINNAT] ou de flucloxacilline:**
  - Prévention des infections staphylococcique méthi-S
  - 2 g voie IV 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 bêta-lactamines; 90 min ou 2 heures avant; **15-20 mg/kg préop dose unique**
  - Suspects d'infections à staphylocoques méti-R [multiples hospitalisations; colonisation avec germes résistants]

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

**De Oliveira J C et al. Circ Arrhythm Electrophysiol 2009; 2: 29-34**

## Revised recommendations (9)

2015	Class	Level	2023	Class	Level
<b><i>Recommendations for cardiovascular implanted electronic device-related infective endocarditis</i></b>					
Routine antibiotic prophylaxis is recommended before device implantation.	<b>I</b>	<b>B</b>	Antibiotic prophylaxis covering <i>S. aureus</i> is recommended for CIED implantation.	<b>I</b>	<b>A</b>
TOE is recommended in patients with suspected cardiac device-related infective endocarditis with positive or negative blood cultures, independent of the results of TTE, to evaluate lead-related endocarditis and heart valve infection.	<b>I</b>	<b>C</b>	TTE and TOE are both recommended in case of suspected CIED-related IE to identify vegetations.	<b>I</b>	<b>B</b>

# BRUISE Study JACC 2016

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY  
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PUBLISHED BY ELSEVIER

VOL. 67, NO. 11, 2016  
ISSN 0735-1097/\$36.00  
<http://dx.doi.org/10.1016/j.jacc.2016.01.009>

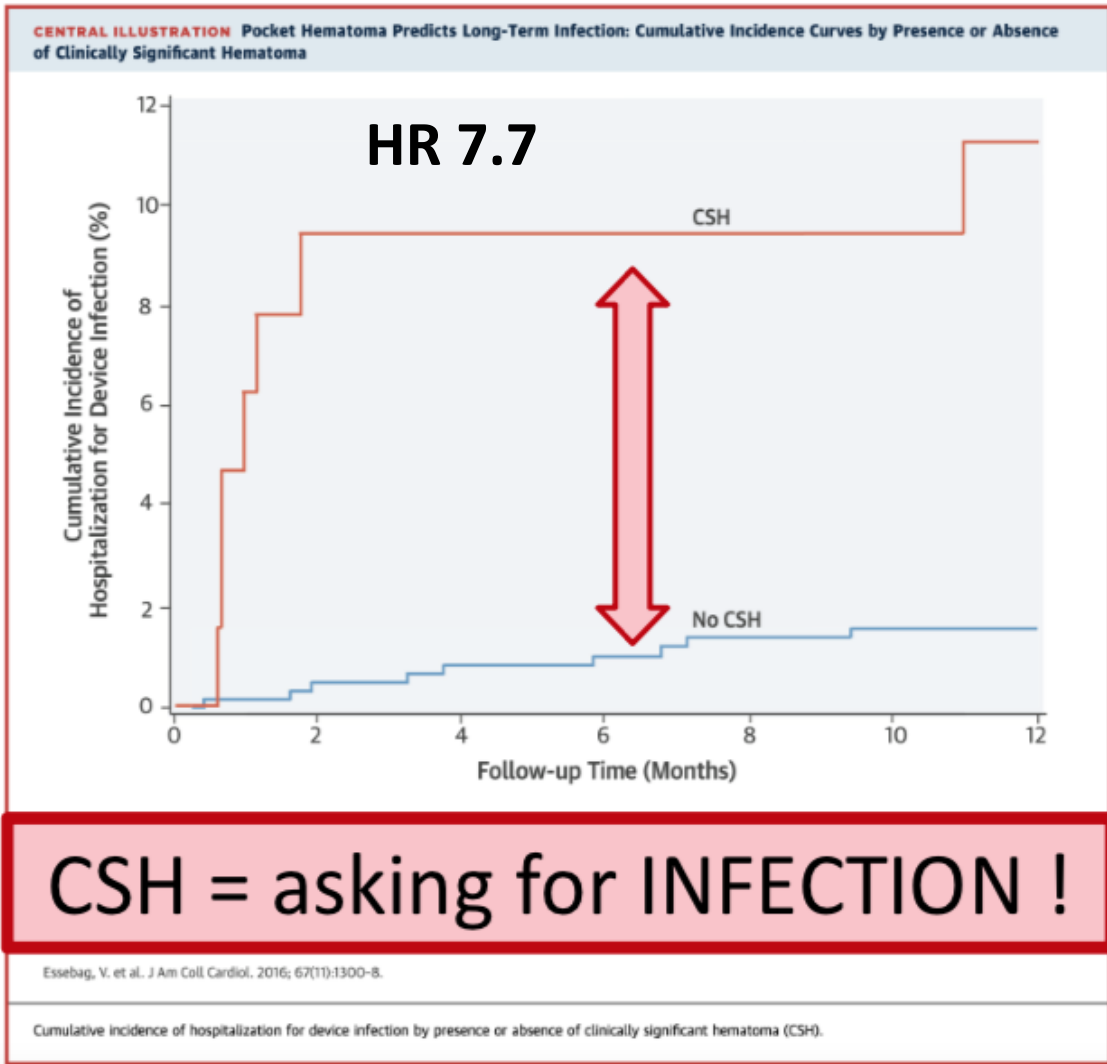
## Clinically Significant Pocket Hematoma Increases Long-Term Risk of Device Infection

### BRUISE CONTROL INFECTION Study

Vidal Essebag, MD, PhD,<sup>a,b</sup> Atul Verma, MD,<sup>c</sup> Jeff S. Healey, MD,<sup>d</sup> Andrew D. Krahn, MD,<sup>e</sup> Eli Kalfon, MD,<sup>a,f</sup> Benoit Coutu, MD,<sup>g</sup> Felix Ayala-Paredes, MD,<sup>h</sup> Anthony S. Tang, MD,<sup>i,j</sup> John Sapp, MD,<sup>k</sup> Marcio Sturmer, MD,<sup>b</sup> Arieh Keren, MD,<sup>l</sup> George A. Wells, PhD,<sup>l</sup> David H. Birnie, MD,<sup>l</sup> for the BRUISE CONTROL Investigators



Multicenter randomized controlled trial  
659 patients



IMPLANTATION

- The overall 1-year DRI rate was 2.4% (16 of 659).
- Infection occurred in 11% of patients (7 of 66) with previous CSH and in 1.5% (9 of 593) without CSH.
- >7-fold increased risk of infection (hazard ratio: 7.7)

# WRAP-IT trial analysis. Heart Rhythm 2021; 18: 2080–2086

## 82% de réduction des infections de loge avec l'enveloppe Tyrx™ en présence d'un hématome

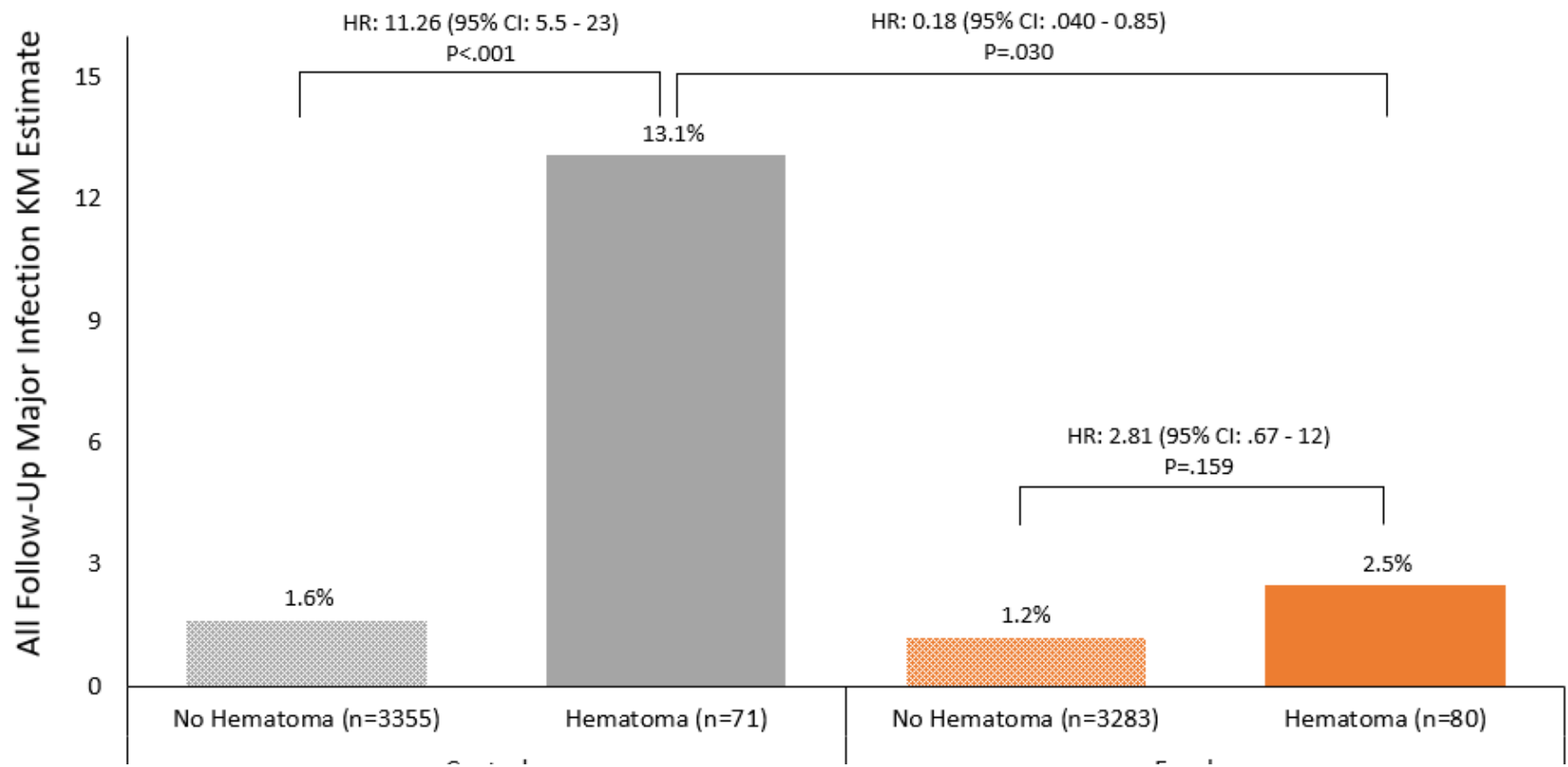
**Titre :** Hematoma and Cardiac Implantable Electronic Device Infection. Insights from the WRAP-IT Trial

**Objectif**  
Examiner l'association entre les hématomes et les infections majeures chez les patients de l'étude WRAP-IT

**Design de l'étude**

- Étude internationale multicentrique, randomisée en 1:1 (TYRX™ vs sans TYRX™)
- N = 6,800 patients\*

**Utilité de l'enveloppe TYREX patients avec risque élevé d'hématome**



**▪ Infectious risk X 11 in WRAP IT in patients with hematoma**

# Management des anticoagulants

Anticoagulants oraux directs	AVK	Double anti-agrégation	OAC + anti-plaquettaires
<ul style="list-style-type: none"> <li>▪ <b>Maintenir les AOD en fonction du score de CHA<sup>2</sup> DS<sup>2</sup>VASc &gt; 3</b></li> <li>▪ <b>ATCD d'AVC/AIT maintien</b></li> </ul>	<p>Maintien avec intervention avec INR entre 2 et 3</p>	<p><b>SCA</b></p> <ul style="list-style-type: none"> <li>- &lt; 6 mois maintien DAPT</li> <li>- &gt; 6 mois arrêt possible</li> </ul> <p>arrêt possible P2Y12 inhibiteurs (5 jours avant)</p>	<p>Maintien des anticoagulants</p>
<ul style="list-style-type: none"> <li>▪ <b>Interruption possible en fonction si CHA<sup>2</sup> DS<sup>2</sup>VASc ≤ 3 :</b></li> <li>- <b>type d'AOD (1/2 vie)</b></li> <li>- <b>clearance à la créatinine</b></li> </ul>	<p>ATCD d'AVC/AIT maintien</p> <p>Prothèses maintien</p>	<p><b>Angioplastie sans SCA</b></p> <ul style="list-style-type: none"> <li>- &lt; 1 mois maintien DAPT</li> <li>- &gt; 1 mois arrêt possible</li> </ul> <p>P2Y12 inhibiteurs (5 jours avant)</p>	<p>Maintien ou non des anti-agrégants en fonction du bénéfice / risque</p> <p><b>(arrêt 5 jours avant si possible)</b></p>

# Enveloppe antibactérienne

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

Gilbert DN et al. The Sanford Guide to Antimicrobial Therapy 2012, 42<sup>th</sup> 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

# Antibacterial Envelope to Prevent Cardiac Implantable Device Infection.

Khaldoun G. Tarakji, et al . N Engl J Med 2019; 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)
	<i>number of patients (percent)</i>			
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.

**Minus 0.5%**

## New recommendations (10)

Recommendations	Class	Level
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### ***Recommendations for cardiovascular implanted electronic device-related infective endocarditis (continued)***

Use of an antibiotic envelope may be considered in select high-risk patients undergoing CIED reimplantation to reduce risk of infection.	<b>IIb</b>	<b>B</b>
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In non- <i>S. aureus</i> CIED-related endocarditis without valve involvement or lead vegetations, and if follow-up blood cultures are negative without septic emboli, 2 weeks of antibiotic treatment may be considered following device extraction.	<b>IIb</b>	<b>C</b>
--	------------	----------

Removal of CIED after a single positive blood culture, with no other clinical evidence of infection, is not recommended.	<b>III</b>	<b>C</b>
--	------------	----------

### ***Recommendations for the surgical treatment of right-sided infective endocarditis***

Tricuspid valve repair should be considered instead of valve replacement, when possible.	<b>IIa</b>	<b>B</b>
--	------------	----------

# Asepsie locale

- Povidone iodée en solution aqueuse à 10%
- Povidone iodée en solution alcoolique à 5%
- Chlorhexidine alcoolique (2%)

La solution est inflammable. Ne pas utiliser de procédures d'électrocautère ou des sources d'inflammation avant que la peau ne soit complètement sèche.



## Chlorhexidine vs Povidone-Iodine Alcohol Solutions for Cardiac Implantable Electronic Devices A Prospective Randomized Study

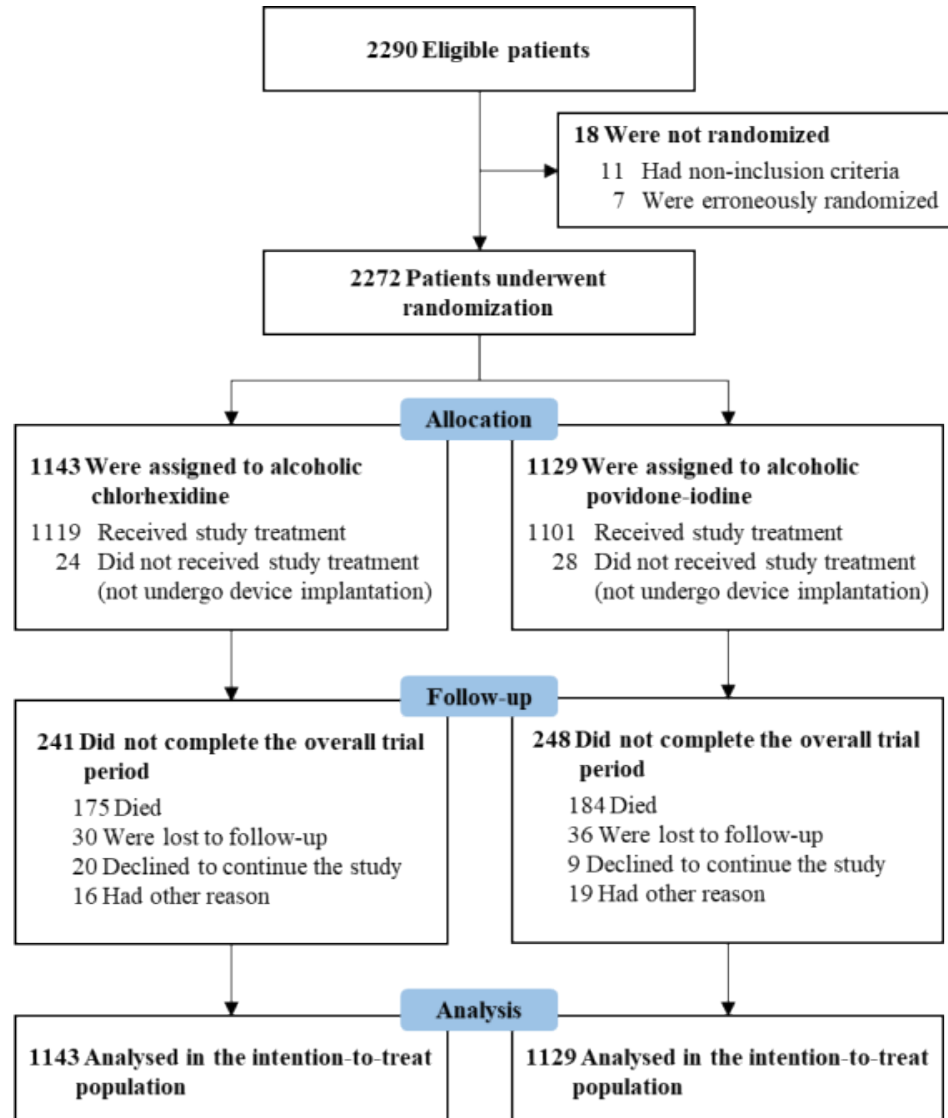
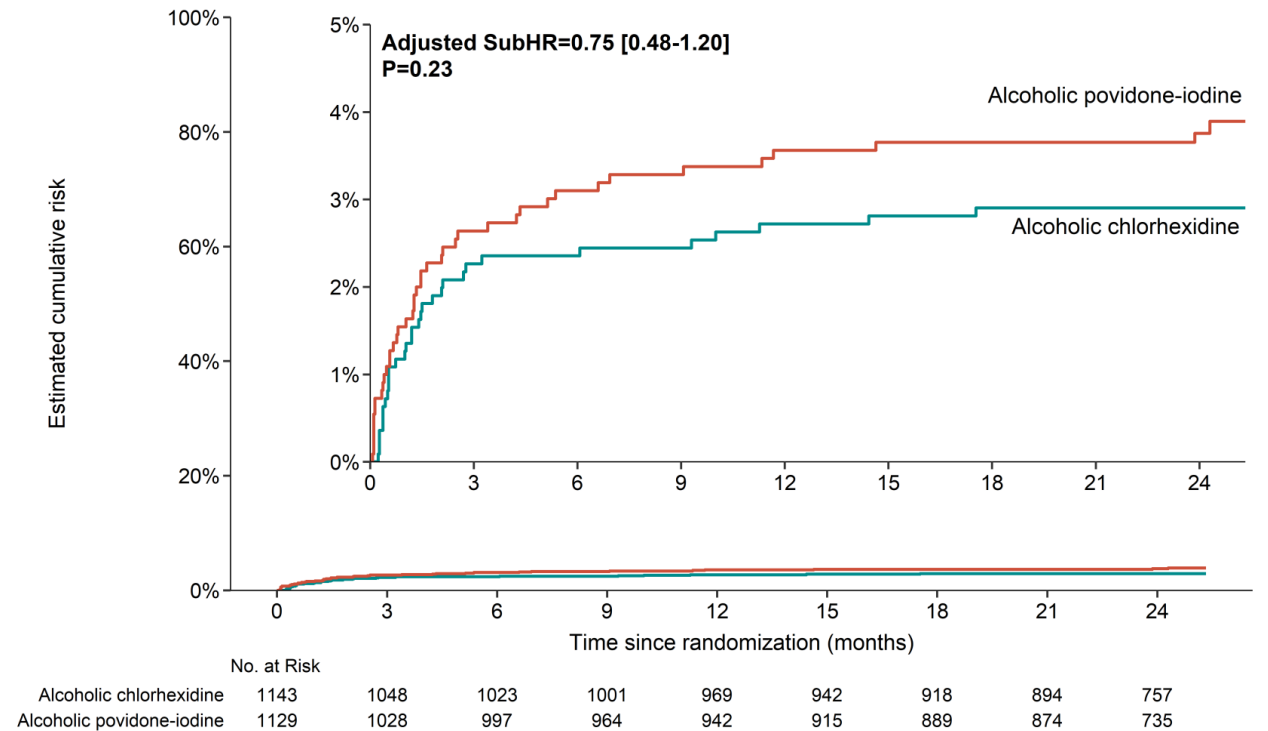
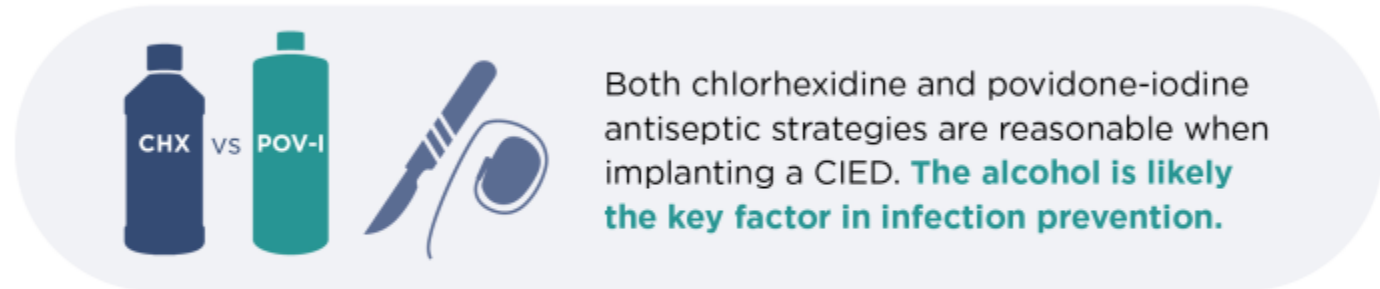


Table 1. Clinical Outcomes during the Trial Period. \*

Outcome	Alcoholic chlorhexidine (N=1143)	Alcoholic povidone-iodine (N=1129)	Treatment Effect (95% CI)	P-value
	Number (percent)			
Primary outcome: local or systemic infection in relation to the implantable device	32 (2.9)	42 (3.9)	0.75 (0.48-1.20)	0.23
Secondary outcomes				
Major cardiovascular events	340 (31.5)	334 (31.3)	1.01 (0.87-1.17)	-





The largest randomized study to date comparing local antiseptic strategies for cardiac device implantation—a clinically meaningful and unresolved question that matters greatly to patients, electrophysiologists, heart failure specialists, and procedural cardiologists.

**TRIAL DESIGN AND POPULATION**

- 21 centers** across France
- 2,272 patients** undergoing CRT
- Randomized 1:1** to chlorhexidine (n = 1,143) or povidone-iodine (n = 1,129)
- Randomization April 2013 to December 2018**

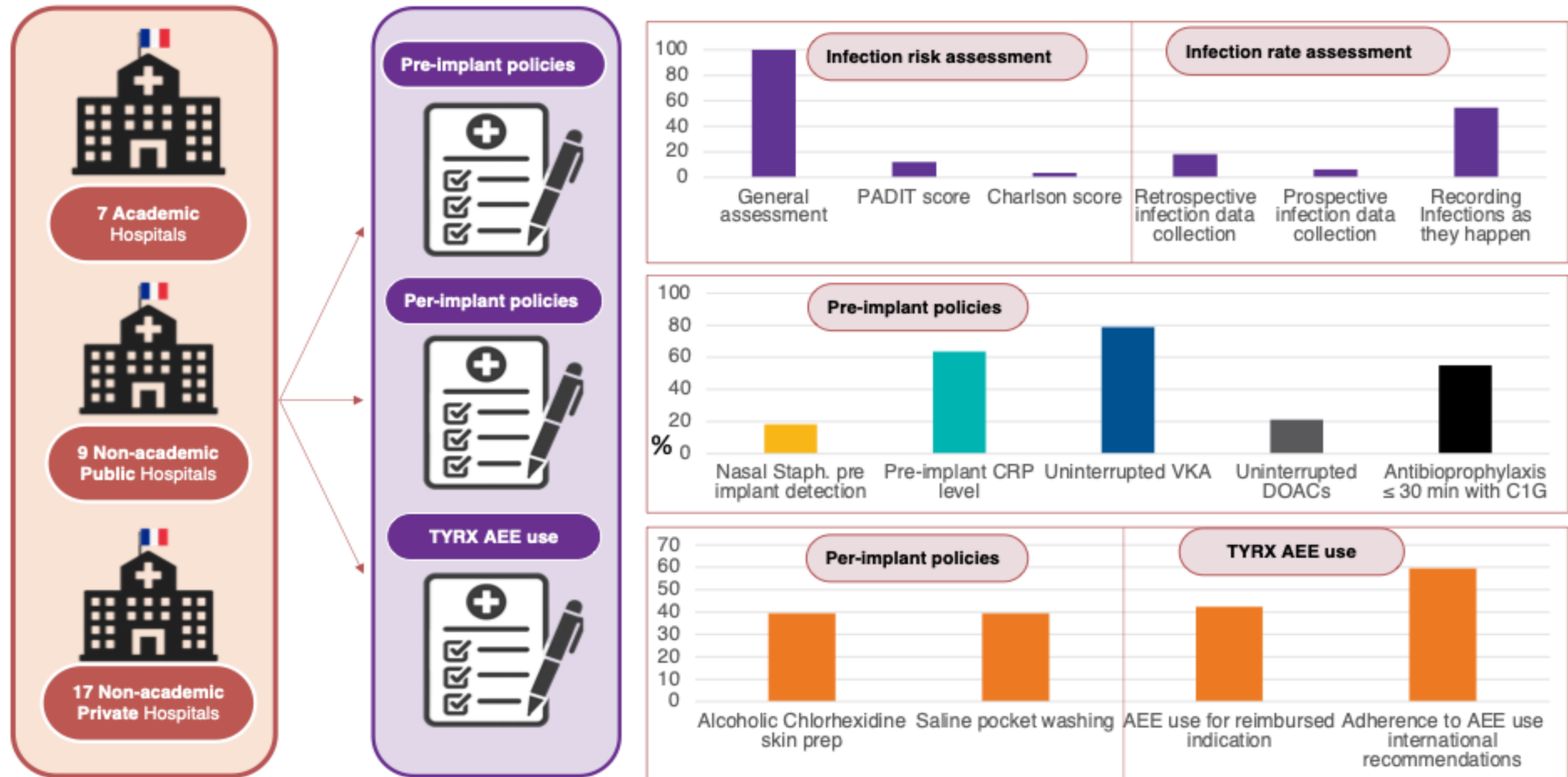
**RESULTS**

PRIMARY OUTCOME	CHX	POV-I
<b>Device-related infections at 24 months</b>	2.9%	3.9%
	(-25%, p = NS)	

SECONDARY OUTCOMES	CHX	POV-I
Major CV events	31.5%	31.3%
Non-infectious side effects	1.6%	1.9%

CRT implantation carries a high infection risk (3.4% overall).

The CHLOVIS trial did not demonstrate a significant reduction in infection rates with 2% alcoholic chlorhexidine compared to alcoholic povidone-iodine.



n = 530 patients from 33 centers

n = 106 practitioners

# CONCLUSIONS

## 1. Mesures préventives classique

- Préparation générale du patient: CRP; fièvre;
- score PADIT.....
- installation
- poche avant la voie d'abord

## 2. Choix de la voie d'abord:

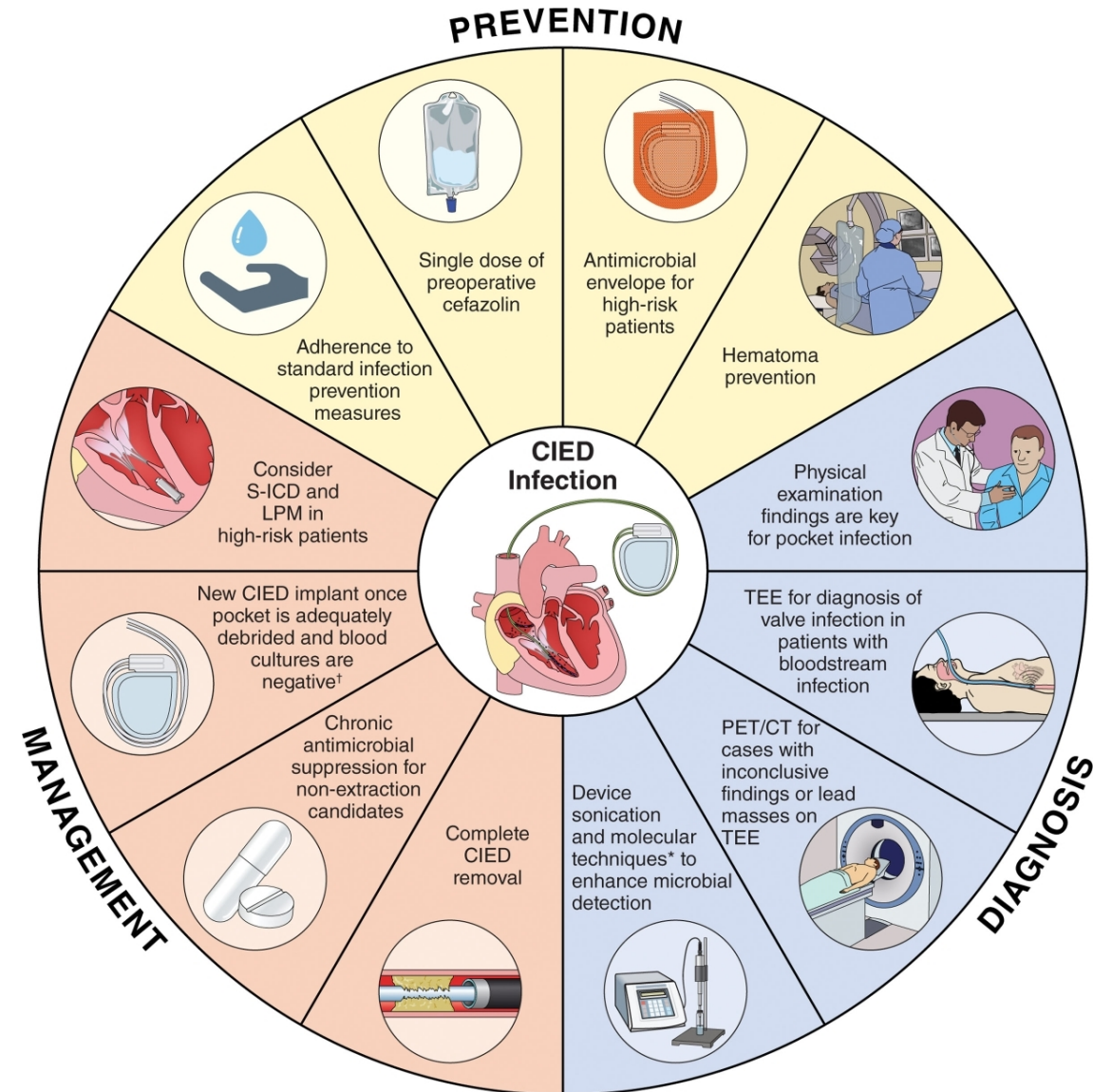
- prévention des complications
- céphalique vs. axillaire / SC

## 3. Prévention du risque infectieux:

- ATB IV
- aseptie locale / chlorhexidine à privilégier
- **Utilisation enveloppe TYREX +++: sous utilisée**

## 4. Prévention du risque d'hématome:

- Gestion des anticoagulants en amont
- Gestion des anti-agrégants
- Risque infectieux OR = 13



\*16S ribosomal RNA gene (rRNA) polymerase chain reaction (PCR)/sequencing or metagenomic next-generation sequencing (mNGS) of sonicate fluid may be helpful in select cases

†Some favor delaying new device placement for up to 14 days after initiation of antimicrobial therapy in the setting of valvular endocarditis