

ELECTRA

Best of recommandations pacing ESC 2021

Gestion des risques



Dr Mondoly – CHU Rangueil - Toulouse

Conflits d'intérêts

- Consultant Abbott, Biotronik, Boston scientific, Medtronic, Microport



ESC

European Society
of Cardiology

European Heart Journal (2021) **00**, 1–94

doi:10.1093/eurheartj/ehab364

ESC GUIDELINES

2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

Developed by the Task Force on cardiac pacing and cardiac resynchronization therapy of the European Society of Cardiology (ESC)

With the special contribution of the European Heart Rhythm Association (EHRA)

Risques

Table 12 Complications of pacemaker and cardiac resynchronization therapy implantation

Incidence of complications after CIED therapy	%
Lead-related reintervention ^{354,639,690,692,695,700,701} (including dislodgement, malposition, subclavian crush syndrome, etc.)	1.0–5.9
CIED-related infections, <12 months ^{354,639,641,645,685,695,702}	0.7–1.7
Superficial infection ³⁵⁴	1.2
Pocket infections ³⁵⁴	0.4
Systemic infections ³⁵⁴	0.5
CIED-related infections, >12 months ^{702–709}	1.1–4.6
Pocket infections ⁷⁰²	1.3
Systemic infections ^{702,705}	0.5–1.2
Pneumothorax ^{354,658,690,692,700,701,707}	0.5–2.2
Haemothorax ⁶⁹⁵	0.1
Brachial plexus injury ⁶⁹⁵	<0.1
Cardiac perforation ^{354,663,690,692,695}	0.3–0.7
Coronary sinus dissection/perforation ^{710,288}	0.7–2.1
Revision due to pain/discomfort ^{354,690}	0.1–0.4
Diaphragmatic stimulation requiring reintervention ^{711,712,665,713}	0.5–5
Haematoma ^{354,639,650,652,654,690,700,714,715}	2.1–5.3
Tricuspid regurgitation ^{716–718}	5–15
Pacemaker syndrome ^{146,701,719}	1–20
Generator/lead problem ^{354,639,690}	0.1–1.5
Deep venous thrombosis (acute or chronic) ^{354,720,721}	0.1–2.6
Any complication ^{354,639,690,692,695,707,722,723}	5–15
Mortality (<30 days) ^{354,694}	0.8–1.4

CIED = cardiovascular implantable electronic device.

Risques liés à la
voie d'abord

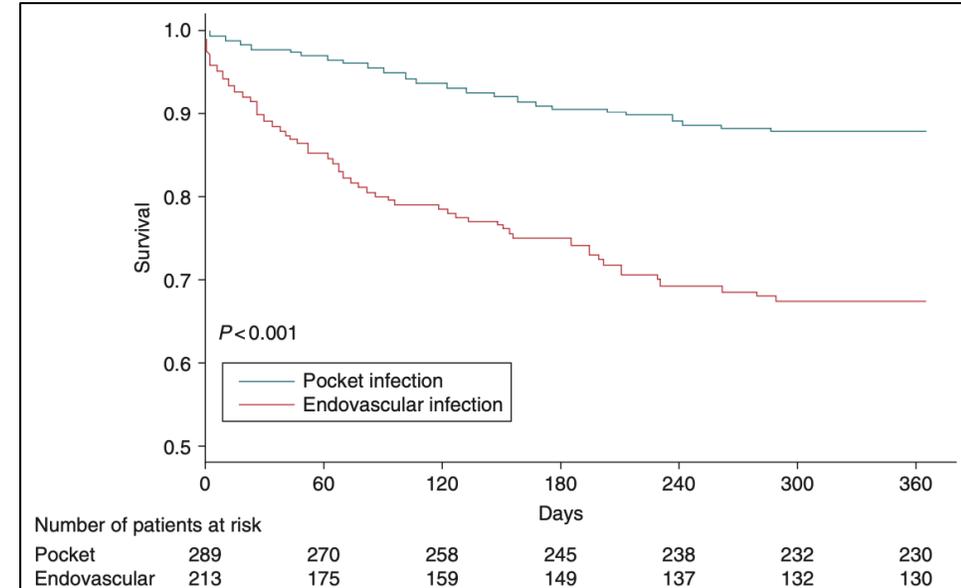
Risque d'insuffisance
tricuspide

Risque
infectieux

Risques liés aux
sondes

Risque infectieux

- Une affection « peu fréquente »
 - Olsen et Al – EHJ 2019 (97750 pts)
 - PM=1,19%
 - DAI=1,91%
 - CRT-P=2,18%
 - CRT-D=3,35%
 - Prutkin et Al – Circulation 2014 (200 909 DAI)
 - DAI simple=1,4%
 - DAI double=1,5%
 - DAI triple=2,0%
- Mais une affection grave



Risque infectieux

TABLE 4. Factors Predictive of Definite Infection

	Percent of Overall Population	Variable*		Analysis					
		Present	Absent	Single Variable			Multiple Variable†		
				OR	95% CI	P	aOR	95% CI	P
Age, mean, y	76	0.14	0.79
Female sex	40.3	0.57	0.77	0.74	0.39–1.40	0.35
Diabetes mellitus	10.1	0.81	0.67	1.21	0.48–3.06	0.61
Immunosuppression	2.4	2.0	0.65	3.07	0.96–9.82	0.08	0.29
Fever 24 h before implant	1.6	5.32	0.61	8.68	3.49–21.6	<10⁻³	5.83	2.00–16.98	<10⁻²
Fever 24 h before implant	1.6	5.32	0.61	8.68	3.49–21.6	<10 ⁻³	5.83	2.00–16.98	<10 ⁻²
Infection at another site	3.8	1.70	0.64	2.64	0.95–7.34	0.08	0.53
Temporary pacing wire	8.8	1.69	0.59	3.58	1.48–8.65	<10⁻²	2.46	1.09–5.13	<10⁻²
PM/ICD	92.8	0.45	0.70	1.56	0.38–6.42	0.77	0.79
Dual-chamber system	62.8	0.75	0.51	1.44	0.70–2.96	0.32
Biventricular system	1.8	1.77	...	3.35	0.74–15.13	0.14	0.45
Local anesthesia	88.5	0.72	0.43	1.69	0.52–5.44	0.62
Ipsilateral intravenous infusion	17.3	0.66	0.69	0.96	0.43–2.15	0.92
Vein puncture	61.7	0.57	0.54	0.80	0.30–2.15	0.65
Procedure duration, min	45	0.56	0.37
>3 Persons in the operating room	27.9	0.93	0.58	1.61	0.87–2.97	0.13	1.49	0.78–2.84	0.23
No wound drain	87.1	0.71	0.56	2.97	0.41–21.59	0.36
Antibiotic prophylaxis	88.3	0.61	1.27	0.48	0.23–0.99	0.05	0.40	0.18–0.86	0.02
Center <100 implantations/y	17.6	0.56	0.71	0.79	0.33–1.87	0.59
Early reintervention	1.7	8.91	0.55	16.29	8.01–33.15	<10⁻⁷	15.04	6.70–33.73	<10⁻⁴
Early reintervention	1.7	8.91	0.55	16.29	8.01–33.15	<10 ⁻⁷	15.04	6.70–33.73	<10 ⁻⁴

Risk Factors Related to Infections of Implanted Pacemakers and Cardioverter-Defibrillators Results of a Large Prospective Study

Didier Klug, MD, PhD; Mamadou Balde, MD; Dominique Pavin, MD; Françoise Hidden-Lucet, MD; Jacques Clementy, MD; Nicolas Sadoul, MD; Jean Luc Rey, MD; Gilles Lande, MD; Arnaud Lazarus, MD; Jacques Victor, MD; Claude Barnay, MD; Bruno Grandbastien, MD; Salem Kacet, MD; for the PEOPLE Study Group

Risque infectieux



European Heart Journal (2019) 40, 1862–1869
doi:10.1093/eurheartj/ehz316

CLINICAL RESEARCH
Arrhythmia/electrophysiology

Incidence of device-related infection in 97 750 patients: clinical data from the complete Danish device-cohort (1982–2018)

Thomas Olsen ^{1*}, Ole Dan Jørgensen^{2,3}, Jens Cosedis Nielsen^{3,4},
Anna Margrethe Thøgersen⁵, Berit Thornvig Philbert⁶, and Jens Brock Johansen^{1,3}

- Reprises (upgrading, changement ou rajout sonde, chgt boitier...)
- ATCD infection de matériel
- Sexe masculin
- Patients jeunes

Table 3 Risk factors for device-related infections

Variable	Devices	Univariate			Multivariable			
		HR	95% CI	P-value	HR	95% CI	P-value	
Sex								
Female	51 484	1			1			
Male	76 561	1.94	1.75	2.14	1.55	1.40	1.72	<0.001
Operation type								
First implant	97 732	1			1			
Replacement	23 332	5.95	5.09	6.95	4.93	4.17	5.84	<0.001
Up-/downgrade	6981	6.91	5.82	8.20	4.39	3.65	5.29	<0.001
Device type								
PM	100 374	1			1			
ICD	16 718	1.83	1.62	2.07	1.26	1.09	1.47	0.002
CRT-P	4630	2.48	2.02	3.04	1.68	1.34	2.11	<0.001
CRT-D	6323	4.19	3.62	4.85	2.22	1.83	2.70	<0.001
Age								
0–20	1171	1.62	1.16	2.25	1.70	1.22	2.37	0.002
21–50	7976	1.36	1.16	1.58	1.40	1.20	1.64	<0.001
51–60	11 847	1.21	1.05	1.40	1.20	1.04	1.39	0.013
61–70	26 714	1			1			
71–80	42 355	0.75	0.66	0.84	0.81	0.72	0.92	0.001
81–90	32 476	0.43	0.37	0.51	0.53	0.45	0.62	<0.001
91+	5506	0.30	0.18	0.48	0.38	0.23	0.61	<0.001
Year of implantation								
1979–89	8871	1.40	1.13	1.72	1.84	1.48	2.29	<0.001
1990–99	20 070	1			1			
2000–09	43 007	1.44	1.23	1.68	1.23	1.05	1.44	0.011
2010–18	56 097	2.06	1.77	2.40	1.42	1.20	1.67	<0.001
Total number of operations								
1	97 750	1			NA			
2	22 851	5.54	4.78	6.43				
3	5452	16.08	12.98	19.91				
4	1401	33.60	24.84	45.43				
5+	591	61.35	41.20	91.36				
Prior infection								
No	125 998	1			1			
Yes	2047	4.36	3.57	5.34	1.65	1.34	2.04	<0.001
Centre								
PM-centre	43 649	1			1			
ICD-centre	84 396	1.36	1.23	1.50	0.89	0.79	0.995	0.041
Complexity								
1–2	63 297	1			1			
3	53 009	1.01	0.91	1.12	1.25	1.10	1.42	0.001
4+	11 739	2.61	2.30	2.96	1.20	1.03	1.40	0.019

Risque infectieux

Rates of and Factors Associated With Infection in 200 909 Medicare Implantable Cardioverter-Defibrillator Implants Results From the National Cardiovascular Data Registry

Jordan M. Prutkin, MD, MHS; Matthew R. Reynolds, MD, MSc; Haikun Bao, PhD;
Jeptha P. Curtis, MD; Sana M. Al-Khatib, MD, MHS; Saurabh Aggarwal, MD; Daniel Z. Uslan, MD

(*Circulation*. 2014;130:1037-1043.)

Table 3. Multivariable Predictors of ICD Infection

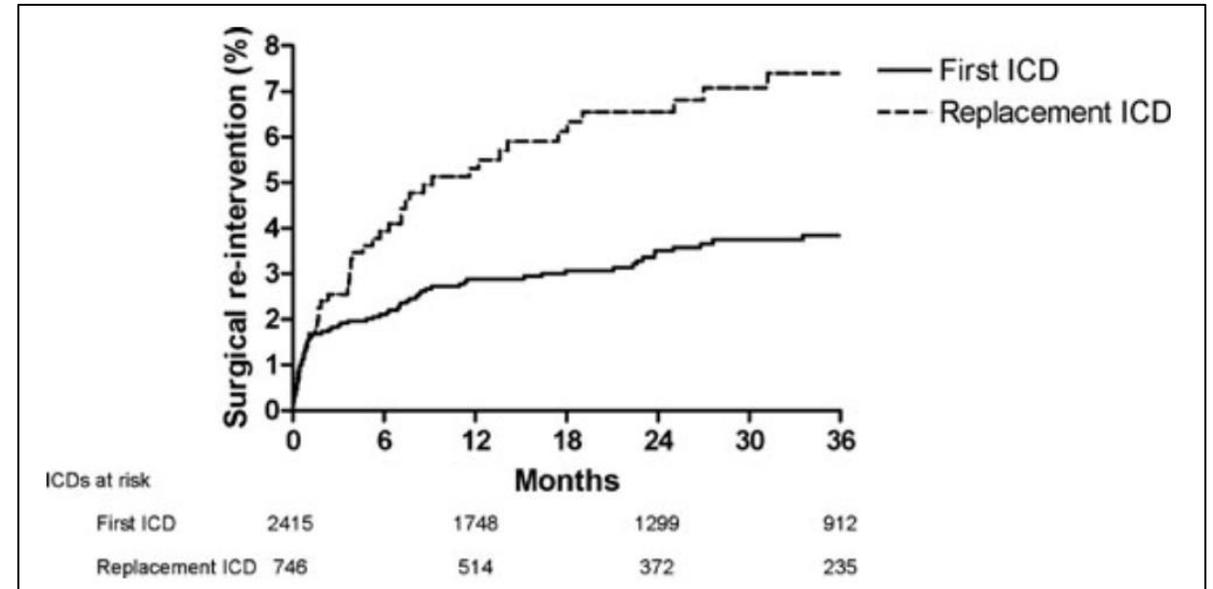
Effect	OR (95% CI)	P Value
Clinical characteristics		
Previous valvular surgery	1.525 (1.375–1.692)	<0.0001
Cerebrovascular disease	1.172 (1.076–1.276)	.0003
Chronic lung disease	1.215 (1.125–1.312)	<0.0001
Renal failure-dialysis	1.342 (1.123–1.604)	.0012
Procedure factors		
Reimplantation		
No	Reference	
Yes-device upgrade, malfunction, manufacturer advisory	1.354 (1.196–1.533)	<0.0001
Yes-battery change	1.090 (0.992–1.198)	
Adverse events	2.692 (2.304–3.145)	<0.0001
Medications		
Warfarin	1.155 (1.060–1.257)	0.001

Risque infectieux

Recurrent Implantable Cardioverter-Defibrillator Replacement Is Associated with an Increasing Risk of Pocket-Related Complications

C. JAN WILLEM BORLEFFS, M.D.,*,‡ JOEP THIJSSSEN, M.D.,*,‡ MIHÁLY K. DE BIE, M.D.,*
JOHANNES B. VAN REES, M.D.,* GUIDO H. VAN WELSENES, M.S.,*
LIESELOT VAN ERVEN, M.D., PH.D.,* JEROEN J. BAX, M.D., PH.D.,*
SUZANNE C. CANNEGIEETER, M.D., PH.D.,† and MARTIN J. SCHALIJ, M.D., PH.D.*

(PACE 2010; 33:1013–1019)



Risque infectieux

Evaluation of risk factors for CIED infection

 **ESC**
European Society
of Cardiology

Europace (2020) 22, 515–516
doi:10.1093/europace/euz246

EHRA CONSENSUS PAPER

European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections—endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), the Latin American Heart Rhythm Society (LAHRS), International Society for Cardiovascular Infectious Diseases (ISCVID) and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)

Non-modifiable

Patient-related factors

End-stage renal disease
Corticosteroid use
Renal failure
History of device infection
COPD
Heart Failure NYHA > II
Malignancy
Diabetes mellitus

Procedure-related factors

Lead repositioning
Device replacement/upgrade

Device-lead-related factors

Device type: CRT or ICD
More than 2 leads
Abandoned / complex route leads
Dual chamber device
Presence of epicardial leads

Risque infectieux

- Gestion pré opératoire:
 - Si fièvre: attendre 24h apyrexie minimum
 - Si TTT antibiotique: 24h après fin du TTT sauf urgence
- Eviter sonde temporaire sinon préférer voie h
- Considérer toutes les possibilités pour éviter
- Décaler la reprise sauf si indispensable



Table 4 Continued

Consensus statement	Statement class	Scientific evidence coding	References
Using local instillation of antiseptic and antibiotics in the pocket		R, E	9
Use of braided sutures for final skin closure		E	
<i>Post-procedural measures</i>			
Use of postoperative antibiotic therapy		R	9
Adequate dressing for 2–10 days is recommended		E	
Patient instructions on wound care should be provided		E	
Delay or reconsider indication for re-intervention if possible		E	
Haematoma drainage or evacuation (unless tense, wound dehiscence is present or pain is severe)		O	24,28

Risque infectieux

- Gestion pré opératoire
 - **Antibioprophylaxie pré opératoire intra veineuse**
 - Cible: staph aureus species (cefazolin ou flucloxacilline)
 - 30-60 min avant incision
 - Vancomycine si allergie ou procédure/patient à risque

**Efficacy of Antibiotic Prophylaxis Before the Implantation
of Pacemakers and Cardioverter-Defibrillators**

**Results of a Large, Prospective, Randomized, Double-Blinded,
Placebo-Controlled Trial**

Julio Cesar de Oliveira, MD; Martino Martinelli, MD; Silvana Angelina D'Orio Nishioka, PhD;
Tânia Varejão, PhD; David Uipe, MD; Anísio Alexandre Andrade Pedrosa, PhD;
Roberto Costa, MD; Stephan B. Danik, MD

(*Circ Arrhythmia Electrophysiol.* 2009;2:29-34.)

Risque infectieux

- Gestion pré opératoire

- **Antibioprophylaxie pré opératoire intra veineuse**

- Cible: staph aureus species (cefazolin ou flucloxacilline)
 - 30-60 min avant incision
 - Vancomycine si allergie ou procédure/patient à risque

- **Antibioprophylaxie post opératoire:**

- Madadi et Al: 450 pts
 - 3 groupes: pas de TTT / antibio 1 jour / antibio 7 jours
 - Pas de différence sur le taux d'infection
 - Krahn et Al: 19603 pts
 - Randomisation: cefazolin pre op vs idem + lavage loge avec AB + 2 jours AB per os
 - Pas de différence significative

Efficacy of Antibiotic Prophylaxis Before the Implantation of Pacemakers and Cardioverter-Defibrillators
Results of a Large, Prospective, Randomized, Double-Blinded, Placebo-Controlled Trial

Julio Cesar de Oliveira, MD; Martino Martinelli, MD; Silvana Angelina D'Orio Nishioka, PhD; Tânia Varejão, PhD; David Uipe, MD; Anísio Alexandre Andrade Pedrosa, PhD; Roberto Costa, MD; Stephan B. Danik, MD

(*Circ Arrhythmia Electrophysiol.* 2009;2:29-34.)

Received: 25 October 2018 | Revised: 10 December 2018 | Accepted: 18 December 2018
DOI: 10.1111/pace.13592

DEVICES WILEY PACE 

Postoperative antibiotic prophylaxis in the prevention of cardiac implantable electronic device infection

Shabnam Madadi MD^{1,2} | Mohammad Kafi MD¹ | Jalal Kheirkhah MD¹ | Amir Azhari MD¹ | Mohammadreza Kiarsi MD¹ | Alireza Mehryar MD¹ | Amirfarjam Fazelifar MD^{1,2} | Abolfath Alizadehdiz MD^{1,2} | Zahra Emkanjoo MD^{1,2} | Majid Haghjoo MD^{1,2} 

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Prevention of Arrhythmia Device Infection Trial

The PADIT Trial 

Risque infectieux

- Gestion per opératoire:
 - Conditions d'asepsie de bloc opératoire

Risque infectieux

- Gestion per opératoire:
 - Conditions d'asepsie de bloc opératoire
- Préparation cutanée
 - Dépilation à la tondeuse et non au rasoir
 - Favoriser l'usage chlorhexidine vs povidone-iodine
 - Darouiche et Al: 849 pts
 - Chirurgie abdo/gynéco/thoracique
 - Favorable chlorhexidine (2 groupes sur 3)
 - Mimoz et Al: 2546 pts
 - Mise en place catheter intra vasculaire en soins intensifs
 - Favorable chlorhexidine



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

Olivier Mimoz, Jean-Christophe Lucet, Thomas Kerforne, Julien Pascal, Bertrand Souweine, Véronique Goudet, Alain Mercat, Lila Bouadma, Sigismund Lasocki, Serge Alfandari, Arnaud Friggeri, Florent Wallet, Nicolas Allou, Stéphane Ruckly, Dorothée Balayn, Alain Lepape, Jean-François Timsit, for the CLEAN trial investigators*

Risque infectieux

- Gestion per opératoire:
 - Lavage de la loge avant mise en place du boîtier
 - Mueller et Al: 540 pts – Laparotomie
 - Lavage loge avec solution antiseptique vs lavage solution saline vs pas de lavage
 - Effet bénéfique lavage vs pas de lavage / pas de comparaison entre les 2 solutions
 - Lakshmanadoss et Al: 327 pts – non randomisé
 - Solution antibiotique vs solution saline
 - Pas de différence sur taux infection

Intraoperative wound irrigation to prevent surgical site infection after laparotomy (IOWISI): study protocol for a randomized controlled trial

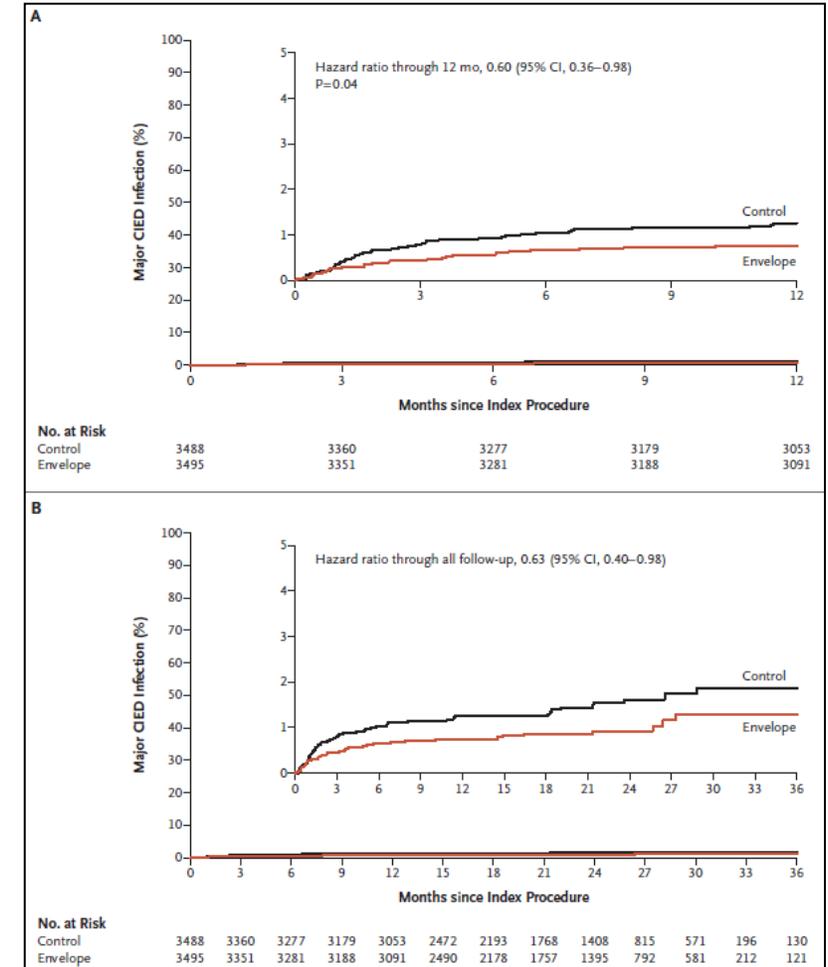
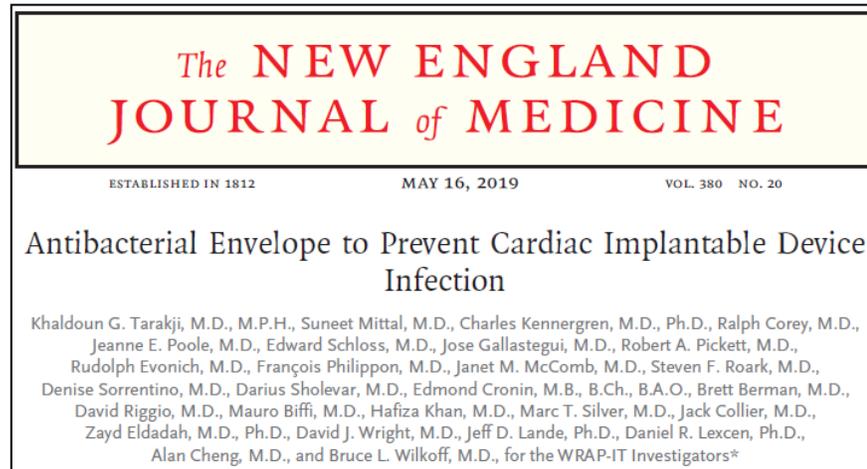
Tara C. Mueller¹, Ulrich Nitsche¹, Victoria Kehl², Rebekka Schirren¹, Beate Schossow³, Ruediger Goess¹, Helmut Friess¹, Daniel Reim^{1*} and on behalf of the IOWISI Study Group

Incidence of Pocket Infection Postcardiac Device Implantation Using Antibiotic versus Saline Solution for Pocket Irrigation

UMASHANKAR LAKSHMANADOSS, M.D.,* BONITA NUANEZ, B.S.,†
ILANA KUTINSKY, D.O.,‡ RIZWAN KHALID, M.D.,§ DAVID E HAINES, M.D., F.A.C.C.,
F.H.R.S.,‡ and WAI SHUN WONG, M.D., M.S.‡

Risque infectieux

- Gestion per opératoire:
 - Enveloppe antibactérienne
 - Wrap-it Study : 6983 pts



Risque infectieux

- Gestion per opératoire:
 - Enveloppe antibactérienne



Indications retenues :

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).

Service Attendu (SA) :	Suffisant
Comparateur retenu :	Autres mesures prophylactiques recommandées dans la prévention des infections liées aux prothèses rythmiques cardiaques
Amélioration du SA :	ASA de niveau III
Type d'inscription :	Nom de marque
Durée d'inscription :	5 ans

Risque infectieux

- Gestion per opératoire:
 - Enveloppe antibactérienne
- Proposition Guidelines 2021:
 - Patients à haut risque d'infection:
 - Insuffisance rénale terminale ou dialysée
 - BPCO
 - Diabétique


HAUTE AUTORITÉ DE SANTÉ

**COMMISSION NATIONALE D'EVALUATION
DES DISPOSITIFS MEDICAUX ET DES TECHNOLOGIES DE SANTE**

AVIS DE LA CNEDiMts
1^{er} septembre 2020

*Faisant suite à l'examen du 30/06/2020, la CNEDiMts a adopté un projet d'avis le 7 juillet 2020.
Ce projet d'avis a fait l'objet d'une phase contradictoire le 01/09/2020. La CNEDiMts a adopté l'avis le 1^{er} septembre 2020.*

CONCLUSIONS

TYRX, enveloppe antibactérienne résorbable
Demandeur : MEDTRONIC France S.A.S. (France)
Fabricant : MEDTRONIC, INC. (Etats Unis d'Amérique)
Les modèles et références proposés par le demandeur (cf. page 3)

Indications retenues :	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 : <ul style="list-style-type: none">- 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).
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Comparateur retenu :	Autres mesures prophylactiques recommandées dans la prévention des infections liées aux prothèses rythmiques cardiaques
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Risque infectieux

- Hématome de loge
 - Hématome = complication fréquente (2,1-9,5% selon les séries)

Risque infectieux

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 - 0,3-2% nécessite une reprise avec risque infectieux multiplié par 15 (Klug et Al – circulation 2007)

Risque infectieux

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 - 0,3-2% nécessite une reprise avec risque infectieux multiplié par 15 (Klug et Al – circulation 2007)
 - Allonge la durée d'hospitalisation et majore la mortalité (2% vs 0,7%) (Sridhar et Al – europe 2015)

Risque infectieux

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 - Hématome = complication fréquente (2,1-9,5% selon les séries)
 - 0,3-2% nécessite une reprise avec risque infectieux multiplié par 15 (Klug et Al – circulation 2007)
 - Allonge la durée d'hospitalisation et majore la mortalité (2% vs 0,7%) (Sridhar et Al – europe 2015)
- Prévention hématome:
 - Hémostase per-opératoire +++
 - Gestion anti thrombotiques

Risque infectieux

• Gestion des anti thrombotiques:

	Dual antiplatelet therapy ^{655,656}		NOAC ⁶⁵²	VKA ⁶⁵⁰	OAC + antiplatelet ⁶⁵⁷
	Thrombotic risk after PCI				
	Intermediate or low >1 month PCI >6 months acute coronary syndrome at index PCI	High <1 month PCI <6 months acute coronary syndrome at index PCI			
Low procedural bleeding risk First implant	Continue aspirin AND Discontinue P2Y ₁₂ inhibitors: Ticagrelor at least 3 days before surgery Clopidogrel at least 5 days before surgery Prasugrel at least 7 days before surgery	<u>Elective surgery:</u> Consider postponement <u>Otherwise:</u> <ul style="list-style-type: none"> Continue aspirin Continue P2Y₁₂ inhibitor 	Continue or interrupt as per operator preference. If interruption, then based on CrCl and specific NOAC	Continue ^a	Continue OAC (VKA ^a or NOAC). Discontinue antiplatelet per patient-specific risk/benefit analysis
High procedural bleeding risk Device exchange, upgrade/revision procedure		Continue aspirin AND Discontinue P2Y ₁₂ inhibitors: Ticagrelor at least 3 days before surgery, Clopidogrel at least 5 days before surgery, Prasugrel at least 7 days before surgery. Bridging with GP IIb/IIIa inhibitors			

Perioperative management of antiplatelet therapy in patients with coronary stents undergoing cardiac and non-cardiac surgery: a consensus document from Italian cardiological, surgical and anaesthesiological societies

EuroIntervention 2014;10:38-46

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Clinically Significant Pocket Hematoma Increases Long-Term Risk of Device Infection
BRUISE CONTROL INFECTION Study

Vidal Essebag, MD, PhD,^{1,2} Atul Verma, MD,³ Jeff S. Healey, MD,⁴ Andrew D. Krahn, MD,⁵ Eli Kalfon, MD,^{6,7} Benoit Coutu, MD,⁸ Felix Ayala-Paredes, MD,⁹ Anthony S. Tang, MD,¹⁰ John Stapp, MD,¹¹ Marcio Starmes, MD,¹² Adesh Keren, MD,¹³ George A. Wells, PhD,¹⁴ David H. Birnie, MD,¹⁵ for the BRUISE CONTROL Investigators

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Pacemaker or Defibrillator Surgery without Interruption of Anticoagulation

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2017 ESC focused update on dual antiplatelet therapy in coronary artery disease developed in collaboration with EACTS

The Task Force for dual antiplatelet therapy in coronary artery disease of the European Society of Cardiology (ESC) and of the European Association for Cardio-Thoracic Surgery (EACTS)

ESC European Society of Cardiology
European Heart Journal (2018) 39, 3912–3919
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CLINICAL RESEARCH
Anti-thrombotic/physiology

Continued vs. interrupted direct oral anticoagulants at the time of device surgery, in patients with moderate to high risk of arterial thrombo-embolic events (BRUISE CONTROL-2)

David H. Birnie^{1,2}, Jeff S. Healey³, George A. Wells⁴, Felix Ayala-Paredes⁵, Benoit Coutu⁶, Glen L. Sumner⁷, Giuliano Becker⁸, Atul Verma⁹, François Philippot¹⁰, Eli Kalfon¹¹, John Elkayim¹², Roopinder K. Sandhu¹³, Pablo B. Nery¹⁴, Nicholas Lelouchis¹⁵, Stuart J. Connolly¹⁶, John Stapp¹⁷, and Vidal Essebag^{1,17}; for the BRUISE CONTROL-2 Investigators

Risque infectieux

- Gestion des anti thrombotiques:

Perioperative management of antiplatelet therapy in patients with coronary stents undergoing cardiac and non-cardiac surgery: a consensus document from Italian cardiological, surgical and anaesthesiological societies

EuroIntervention 2014;10:38-46

Table 2. Cardiac surgery.

		Thrombotic risk			
		Low risk	Intermediate risk	High risk	
Haemorrhagic risk	Low risk	–	–	–	
	Intermediate risk	<ul style="list-style-type: none"> – Minithoracotomy – TAVI (apical approach) – OPCAB – CABG – Valve replacement 	ASA: continue P2Y ₁₂ receptor inhibitors: - Discontinue 5 days before ^a - Resume within 24-72 hours, with a loading dose	Elective surgery: postpone Non-deferrable surgery: ASA: continue P2Y ₁₂ receptor inhibitors: - Discontinue 5 days before ^a - Resume within 24-72 hours, with a loading dose	Elective surgery: postpone Non-deferrable surgery: ASA: continue P2Y ₁₂ receptor inhibitors: - Discontinue 5 days before ^a - Resume within 24-72 hours, with a loading dose Bridge therapy with GP IIb/IIIa inhibitors ^b
	High risk	<ul style="list-style-type: none"> – Reintervention – Endocarditis – CABG in PCI failure – Aortic dissections 	ASA: continue P2Y ₁₂ receptor inhibitors: - Discontinue 5 days before ^a - Resume within 24-72 hours, with a loading dose	Elective surgery: postpone Non-deferrable surgery: ASA: continue P2Y ₁₂ receptor inhibitors: - Discontinue 5 days before ^a - Resume within 24-72 hours, with a loading dose	Elective surgery: postpone Non-deferrable surgery: ASA: continue P2Y ₁₂ receptor inhibitors: - Discontinue 5 days before ^a - Resume within 24-72 hours, with a loading dose Bridge therapy with GP IIb/IIIa inhibitors ^b

^a 7 days prior for prasugrel; ^b collegial discussion of risk, even with family/patient. References^{30,31,33,55-60,74,79-87,89}. ASA: aspirin; CABG: coronary artery bypass grafting; OPCAB: off-pump coronary artery bypass; PCI: percutaneous coronary intervention or coronary angioplasty; TAVI: transcatheter aortic valve implantation

Risques liés à la voie d'abord

- Voies d'abord veineuses: sous clavière, axillaire ou céphalique

	Total	AP	CV	SP	P-value
No. of attempts	681	251	271	159	
No. of successful attempts	611	245	212	154	
Success rate (%)	89.7	97.6	78.2	96.8	AP vs. CV (<0.001) SP vs. CV (<0.001) AP vs. SP (0.525)

Europace (2017) **19**, 1193–1197

- 2 types de complications:

- Complications locales (Pneumothorax, hemo-pneumothorax, ponction artérielle, atteinte plexus brachial)
- Détérioration de la sonde

Risques liés à la voie d'abord

- Complications locales:
 - Pneumothorax:
 - Incidence= 0,66%
 - Voie d'abord: SC 42% / céphalique=47% / double 8%
 - Facteurs favorisants:
 - Sexe féminin (x1,9)
 - Age>80ans (x1,4)
 - ATCD BPCO (x3,9)
 - PM double chambre (x1,5)
 - Abord sous clavier (x7,8)
 - Implantation dans un centre non universitaire (x2,1)



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Europace (2012) 14, 1132–1138
doi:10.1093/europace/eus054

CLINICAL RESEARCH
Pacing and Resynchronization Therapy

Pneumothorax in cardiac pacing: a population-based cohort study of 28 860 Danish patients

Rikke Esberg Kirkfeldt^{1,4*}, Jens Brock Johansen^{2,4}, Ellen Aagaard Nohr³, Mogens Moller^{2,4}, Per Arnsbo^{2,4}, and Jens Cosedis Nielsen¹

Risques liés à la voie d'abord

- Complications locales:
 - Comparaison axillaire/sous clavière:

- Apport approche échoguidée:

Optimized Axillary Vein Technique versus Subclavian Vein Technique in Cardiovascular Implantable Electronic Device Implantation: A Randomized Controlled Study

Peng Liu, Yi-Feng Zhou, Peng Yang, Yan-Sha Gao, Gui-Ru Zhao, Shi-Yan Ren, Xian-Lun Li
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Table 3: Complications in perioperative period and follow-ups

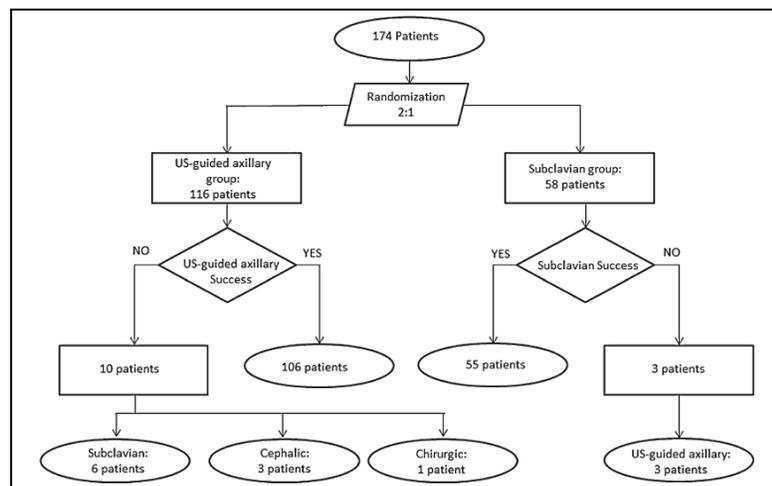
Variables	Axillary vein group (n = 125)	Subclavian vein group (n = 122)	χ^2	P
Pneumothorax	0	3	3.099	0.119
Difficulty of lead operating	0	3	3.099	0.119
Lead dislocation	1	1	0.000	1.000
Infection	1	1	0.000	1.000
Subclavian crush syndrome	0	2	2.058	0.243
Total	2	10	5.813	0.016

Journal of Interventional Cardiac Electrophysiology (2018) 51:153–160
<https://doi.org/10.1007/s10840-018-0313-7>

Efficacy of ultrasound-guided axillary/subclavian venous approaches for pacemaker and defibrillator lead implantation: a randomized study

Mattia Liccardo¹ · Pasquale Nocerino² · Salzano Gaia³ · Carmine Ciardiello⁴ 

➔ 2 PTX en SC vs 0 en axillaire



Risques lié à la voie d'abord

- Détérioration de la sonde:

	Total	AP	CV	SP	P-value
No. of attempts	681	251	271	159	
No. of successful attempts	611	245	212	154	
Success rate (%)	89.7	97.6	78.2	96.8	AP vs. CV (<0.001) SP vs. CV (<0.001) AP vs. SP (0.525)
Lead failure					
No. of leads	681	252	217	212	
Conductor coil fracture, <i>n</i> (%)	9 (1.3)	0	3 (1.4)	6 (2.8)	
Insulation failure, <i>n</i> (%)	11 (1.6)	3 (1.2)	2 (0.9)	6 (2.8)	
Total, <i>n</i> (%)	20 (2.9)	3 (1.2)	5 (2.3)	12 (5.6)	
Follow-up duration (months)	73.6 ± 33.1	66.5 ± 28	78.8 ± 34.7	77.9 ± 35.3	<0.001

Europace (2017) **19**, 1193–1197

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Efficacy of ultrasound-guided axillary/subclavian venous approaches for pacemaker and defibrillator lead implantation: a randomized study

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Variable	Ultrasound-guided axillary group (<i>n</i> = 116)	Subclavian group (<i>n</i> = 58)	<i>P</i> value
Lead fracture, <i>n</i> (%)	2 (1.7)	2 (3.4)	0.865
Insulation defect, <i>n</i> (%)	1 (0.9)	1 (1.7)	0.775
Total of lead complications, <i>n</i> (%)	3 (2.6)	3 (5.2)	0.664

Risques liés aux sondes

- Selon le type de sonde:
 - Kirkfeldt et Al – Heart rhythm 2011:
 - Sonde OD: 2,3%
 - Sonde VD: 2,2%
 - Sonde VG: 4,3%
- Selon le type de risque
 - Risque de dégradation de la fonction VG
 - Risque de perforation OD ou VD
 - Risque de déplacement ou autre

Risques liés aux sondes

- Risque de dégradation de la fonction VG

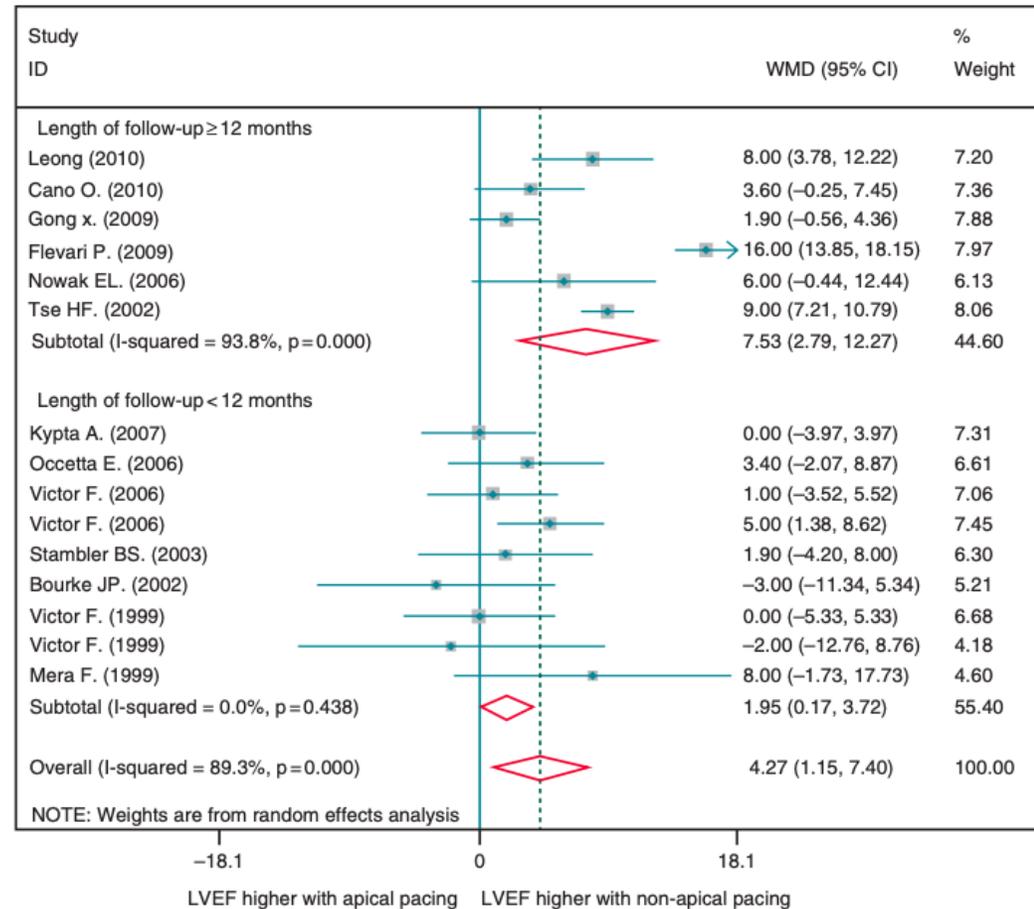

 Europace (2012) 14, 81–91
 doi:10.1093/europace/eur240

CLINICAL RESEARCH
Pacing and Resynchronization Therapy

Beneficial effects of right ventricular non-apical vs. apical pacing: a systematic review and meta-analysis of randomized-controlled trials

Avi Shimony^{1,2*}, Mark J Eisenberg¹, Kristian B. Filion³, and Guy Amit²

➔ *Place d'une stimulation plus physiologique (his?, branche gauche?)*



Risques liés aux sondes

- Risque de perforation selon type de sonde:
 - Migliore et Al – 3815 pts
 - Pas de différence entre sonde active(0,5%) et passive (0,3)
 - Pas de différence entre sonde DAI(0,3%) et PM (0,4%)
 - Segreti et Al – 637 pts extraits
 - Association entre développement adhérences intra cardiaques avec sondes passives (OR à 3,25)
 - Sondes double coil associées à plus d'adhérences (OR à 3,25)

Incidence, Management, and Prevention of Right Ventricular Perforation by Pacemaker and Implantable Cardioverter Defibrillator Leads

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EMANUELE BERTAGLIA, M.D.,* LOIRA LEONI, M.D., Ph.D.,*
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BARBARA IGNATIUK, M.D.,† MARTA VERONESE, M.D.,‡ ROBERTO VERLATO, M.D.,§
GIUSEPPE TARANTINI, M.D., Ph.D.,* SABINO ILCETO, M.D.,*
and DOMENICO CORRADO, M.D., Ph.D.*

Major predictors of fibrous adherences in transvenous implantable cardioverter-defibrillator lead extraction

Luca Segreti, MD, Andrea Di Cori, MD, Ezio Soldati, MD, Giulio Zucchelli, MD, PhD,
Stefano Viani, MD, Luca Paperini, MD, Raffaele De Lucia, MD, Giovanni Coluccia, MD,
Sergio Valsecchi, PhD, Maria Grazia Bongiorno, MD, FESC

Risques liés aux sondes

- Risque de perforation selon site d'implantation:
 - Cano et Al – 3800 pts
 - Facteurs prédictifs perforation (0,8%):
 - Position apicale de la sonde
 - Âge > 80 ans
 - Sexe féminin



Risques liés aux sondes

- Risque spécifique à la sonde VG:
 - Bénéfice net des sondes quadripolaires :
 - Diminution des stimulations phréniques
 - Diminution des déplacements nécessitant reprise
 - Amélioration de la mortalité

Performance and clinical comparison between left ventricular quadripolar and bipolar leads in cardiac resynchronization therapy: Observational research

M. Ziacchi^{a,*}, G. Zucchelli^b, D. Ricciardi^c, G. Morani^d, E. De Ruvo^e, V. Calzolari^f, S. Viani^b, V. Calabrese^c, L. Tomasi^d, L. Calò^e, L. De Mattia^f, M.G. Bongiorno^b, G. Boriani^{a,b,c,d,e,f,g}, M. Biffi^a

Cardiac Resynchronization Therapy Delivered Via a Multipolar Left Ventricular Lead is Associated with Reduced Mortality and Elimination of Phrenic Nerve Stimulation: Long-Term Follow-Up from a Multicenter Registry

JONATHAN M. BEHAR, M.B.B.S., M.R.C.P.,^{*,†} JULIAN BOSTOCK, Ph.D., F.H.R.S.,^{*,†} ADRIAN PO ZHU LI, B.A., B.M.B.Ch.,[†] HUI MEN SELINA CHIN, B.A.,[†] STEPHEN JUBB, B.A., B.M.B.Ch.,[†] EDWARD LENT, B.A.B.M., B.Ch.,[†] JAMES GAMBLE, M.B.B.S., M.R.C.P.,[†] PAUL W.X. FOLEY, M.D., F.R.C.P.,^{‡,§} TIM R. BETTS, M.D., F.R.C.P.,[†] CHRISTOPHER ALDO RINALDI, M.D., F.R.C.P., F.H.R.S.,^{*,†} and NEIL HERRING, D.Phil., M.R.C.P.,^{†,‡}

Improved implant and postoperative lead performance in CRT-D patients implanted with a quadripolar left ventricular lead. A 6-month follow-up analysis from a multicenter prospective comparative study

Giovanni B. Forleo · Luigi Di Biase · Germana Panattoni · Massimo Mantica ·

Risques liés aux sondes

- Synthèse sur le choix des sondes:
 - Pour le VD, préférer le septum et donc les sondes actives
 - Pour l'OD, éviter la paroi libre
 - Quadripolaire au niveau du sinus coronaire
 - Plutôt des mono coils pour le DAI

Risque insuffisance tricuspide

- Prévalence fuite grade 2 ou plus: 10-39% selon séries
- Prévalence plus grande si PM/DAI
- Mécanismes:
 - Dégât sur les feuillets ou l'appareil sous valvulaire lors de l'implantation
 - Dysfonction d'un ou des feuillets secondaire à la présence chronique de la sonde
- Traitement:
 - Préventif: limiter le nb de sonde VD, leadless +++
 - Curatif: extraction seule (?), chirurgical principalement, percutané (?)

REVIEW TOPIC OF THE WEEK

Tricuspid Valve Dysfunction
Following Pacemaker or
Cardioverter-Defibrillator Implantation

James D. Chang, MD,^a Warren J. Manning, MD,^{a,b} Elisa Ebrille, MD,^a Peter J. Zimetbaum, MD^a

Conclusion

- Risques sont nombreux et très variables
- Gestion passe par:
 - Connaissance des groupes à risques
 - Connaissance des situations à risques
 - Pratique codifiée et systématisée lors des implantations
- Les recommandations oublient totalement la gestion post opératoire +++
- Evolutions techniques vont probablement améliorer cette gestion
 - Leadless: taux infection faible, pas de passage de la tricuspide,....
 - Stim branche gauche: moins d'effet délétère sur la fonction VG, moins de sonde pour resynchroniser???