RHYTHM 2015

Arrhythmias & Heart Failure: New Insights & Technological Advances

Palais du Pharo, Marseille, France May 28-30, 2015

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IRM et Prothèses Implantables

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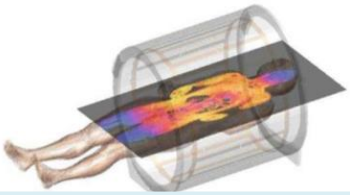
CHAMP MAGNETIQUE

STATIQUE

GRADIENT



RADIOFREQUENCE

INTERFERENCES

BRUIT ++++

- ➔FREQUENCE INNAPROPRIEE
- ➔MODE SECOURS (reset mode)
- ➔**INHIBITION STIMULATION**
- ➔**DAI : THERAPIE INNAPROPRIEE**

LESION +

- ➔ INTERFACE TISSU/SONDE
- ➔GENERATEUR

PMK/DAI (Système) IRM “COMPATIBLE”

➔ Juin 2011: 1 er PMK (MEDTRONIC)

➔ Novembre 2012: 1 er DAI (BIOTRONIK)

*Marqueur radiographique

*Interrupteur à lame => système hall sensor

*Filtre sur sonde et changement géométrie

*Réduction des composants ferromagnétiques

*Software: stop stockage arythmie per IRM

PMK IRM COMPATIBLE : ESSAI CLINIQUE

Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment

Bruce L. Wilkoff, MD, FHRS, CCDS,* David Bello, MD,† Milos Taborsky, MD, PhD, FESC,‡ Josef Vymazal, MD, PhD,‡ Emanuel Kanal, MD, FACR, FISMRM,§ Hubertus Heuer, MD,‖ Katrin Hecking, MD,‖ W. Ben Johnson, MD, CCDS,¶ William Young, MD,¶ Brian Ramza, MD, PhD,** Naveed Akhtar, MD,** Bernhard Kuepper, MD,†† Peter Hunold, MD,†† Roger Luechinger, PhD,‡‡ Helmut Puererfellner, MD,§§ Firat Duru, MD,‖‖ M.J.W. Gotte, MD,*** Richard Sutton, MD, PhD,††† Torsten Sommer, MD‡‡‡; on behalf of the EnRhythm MRI SureScan Pacing System Study Investigators

Heart Rhythm 2011

RESULTS No MRI-related complications occurred during or after MRI, including sustained ventricular arrhythmias, pacemaker inhibition or output failures, electrical resets, or other pacemaker malfunctions. Pacing capture threshold and sensed electrogram amplitude changes were minimal and similar between study groups.

CONCLUSION This trial documented the ability of this pacemaker system to be exposed in a controlled fashion to MRI in a 1.5 T scanner without adverse impact on patient outcomes or pacemaker system function.

RECOMMANDATIONS ESC 2013

Recommendations	Class	Level
1) Conventional cardiac devices. In patients with conventional cardiac devices, MRI at 1.5 T can be performed with a low risk of complications if appropriate precautions are taken (see additional advice).	IIb	B
2) MRI-conditional PM systems. In patients with MRI-conditional PM systems, MRI at 1.5 T can be done safely following manufacturer instructions.	IIa	B

ESC guidelines, Eur Heart J (2013) 34 (29): 2281-2329

IRM COMPATIBLE = IRM CONDITIONNEL SELON RECO INDUSTRIEL

Boston Scientific	Medtronic	St. Jude Medical	BIOTRONIK	SORIN GROUP
ACCOLADE MRI™	ADVISA™	ACCENT MRI™	ELUNA™	KORA™
Ingevity™ (6F)	CaptureFix Novus (7F)	Tendril MRI (8F)	Solia (6F)	Beflex (7F)
Corps entier	Corps entier	Corps entier	Corps entier	Exclusion zone thoracique. Taille > 1,47 m
Sans limitation de temps	Sans limitation de temps	Sans limitation de temps	Sans limitation de temps	40 min
1,5 T et 3 T	1,5 T	1,5 T	1,5 T	1,5 T
4 W/kg	2 W/kg	4 W/kg	4 W/kg	2 W/kg
Désactivation du mode IRM				
Minuterie automatique Off, 12, 24, 48 h ou programmateur	Avec le programmateur	Télécommande « Activator »	Avec le programmateur	Automatiquement, 5 min. après que le dispositif ait quitté le champ IRM

1- Fozia Z. Ahmed, and al. Not All Pacemakers Are Created Equal : MRI Conditional Pacemaker and Lead Technology. Clinical reviews – J Cardiovasc Electophysiol, Vol.24,pp. 1059-1065, September 2013. Doi : 10.1111/jce.12238.
8- Edward T. Martin and al. Magnetic Resonance Imaging and Cardiac Pacemaker Safety at 1.5-Tesla - Journal of the American College of Cardiology

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ESC guidelines, Eur Heart J (2013) 34 (29): 2281-2329

IRM et PMK CONVENTIONNEL : RISQUE TRES FAIBLE

Determining the Risks of Magnetic Resonance Imaging at 1.5 Tesla for Patients With Pacemakers and Implantable Cardioverter Defibrillators

Jennifer D. Cohen, MD, Heather S. Costa, PhD, and Robert J. Russo, MD, PhD*

Primary and secondary end point events in the magnetic resonance imaging group

End Point	Number of Events/Number of Events Possible (%) [95% Confidence Interval]
Primary end point events	
Death	0/125 (0%) [0%–3%]
Device failure	0/125 (0%) [0%–3%]
Lead failure	0/259 (0%) [0%–1%]
Atrial/ventricular arrhythmia	0/125 (0%) [0%–3%]
Loss of capture	0/125 (0%) [0%–3%]
Electrical reset	0/125 (0%) [0%–3%]
Secondary end point events	
Battery voltage decrease ≥0.04 V	4/90 (4%) [2%–11%]
Pacing lead threshold increase ≥0.5 V	5/195 (3%) [1%–6%]
P-wave amplitude decrease ≥50%	1/65 (2%) [0.3%–8%]
R-wave amplitude decrease ≥25%	2/74 (3%) [1%–9%]
Pacing lead impedance change ≥50 Ω	13/210 (6%) [4%–10%]
High-voltage impedance change ≥3 Ω	2/17 (12%) [3%–34%]

Am J Cardiol 2012

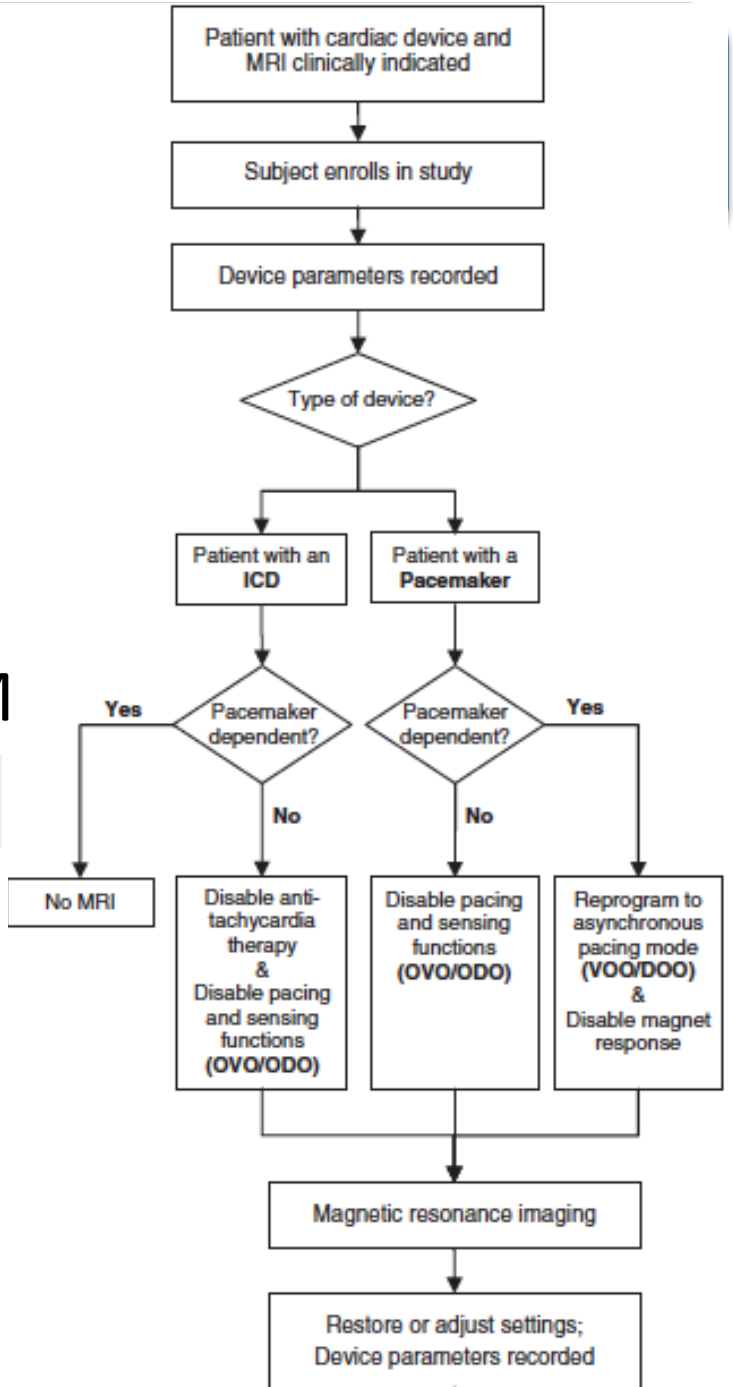
REGISTRE MAGNASAFE

- ➔ 1000 PMK conventionnel
- ➔ 500 DAI conventionnel
- ➔ IRM 1,5 T , non thoracique
- ➔Controle pré et post IRM
- ➔Surveillance médicale per IRM

Table II. Primary and secondary outcomes during or immediately after the MRI scan

Primary outcomes
- Death during the scan
- Device failure requiring immediate replacement
- Lead failure requiring immediate replacement
- Induced arrhythmia (new-onset atrial fibrillation during the MRI scan, symptomatic bradycardia with a heart rate <40 beats/min, ventricular tachycardia, or ventricular fibrillation)
- Loss of capture during the scan
- Electrical reset during the scan

Secondary outcomes
- Decrease in battery voltage ≥0.04 V
- Increase in pacing threshold ≥0.50 V at 0.4 ms or any increase at a wider pulse width
- Decrease in P-wave measurement ≥50%
- Decrease in R-wave measurement ≥25%
- Increase or decrease in pacing lead impedance ≥50 Ω
- Increase or decrease in shock lead impedance ≥3 Ω



REGISTRE MAGNASAFE : RESULTATS

AHA Nov 2014

- ➔ 0 décès,
- ➔ 0 dysfonction sonde
- ➔ 0 perte capture
- ➔ 6 PMK mode reset partiel sans incidence
- ➔ 1 DAI remplacé (thérapies sur ON en pré IRM…)

CLASSIFICATION RISQUE IRM

ASTM (American Society of Test and Measurement)

SANS DANGER « Safe »

Le dispositif peut évoluer dans un environnement IRM quelles que soient les conditions

SANS DANGER SOUS CERTAINES CONDITIONS « Conditional »

Le dispositif est compatible avec un environnement IRM, en respectant certaines conditions

POTENTIELLEMENT DANGEREUX « Unsafe »

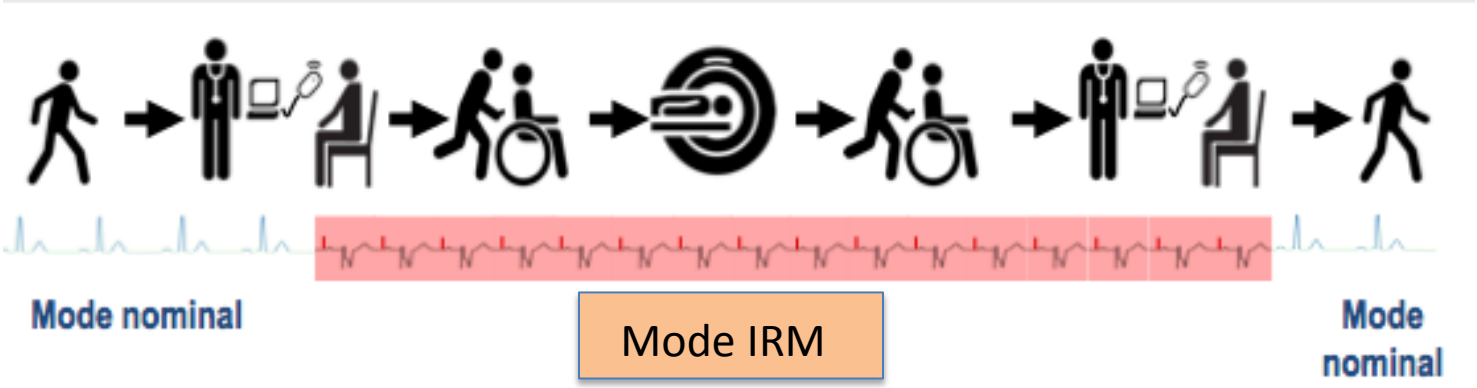
Le dispositif n'est pas sûr dans un environnement IRM, quelles que soient les conditions

Hundley WG et al. expert consensus documents J. Am. Coll. 2010

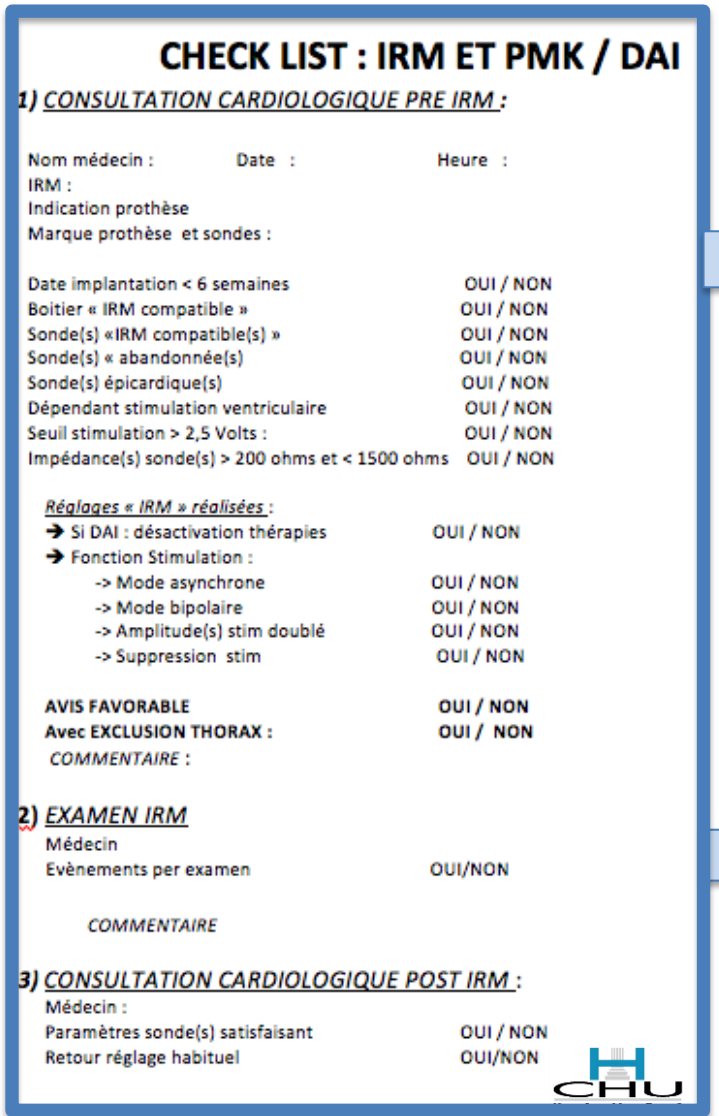
CIRCUIT PATIENT

(toutes prothèses)

SI EXAMEN JUSTIFIE et IRM JUSQU'A 1,5 T



TRACABILITE, EVALUATION RISQUE D'INTERFERENCE



CHECK LIST : IRM ET PMK / DAI

1) ***CONSULTATION CARDIOLOGIQUE PRE IRM :***

Nom médecin : Date : Heure :
IRM :
Indication prothèse
Marque prothèse et sondes :

Date implantation < 6 semaines OUI / NON
Boitier « IRM compatible » OUI / NON
Sonde(s) «IRM compatible(s) » OUI / NON
Sonde(s) « abandonnée(s) OUI / NON
Sonde(s) épicardique(s) OUI / NON
Dépendant stimulation ventriculaire OUI / NON
Seuil stimulation > 2,5 Volts : OUI / NON
Impédance(s) sonde(s) > 200 ohms et < 1500 ohms OUI / NON

Réglages « IRM » réalisées :
➔ Si DAI : désactivation thérapies OUI / NON
➔ Fonction Stimulation :
-> Mode asynchrone OUI / NON
-> Mode bipolaire OUI / NON
-> Amplitude(s) stim doublé OUI / NON
-> Suppression stim OUI / NON

AVIS FAVORABLE OUI / NON
Avec EXCLUSION THORAX : OUI / NON
COMMENTAIRE :

2) ***EXAMEN IRM***
Médecin
Evènements per examen OUI/NON

COMMENTAIRE

3) ***CONSULTATION CARDIOLOGIQUE POST IRM :***
Médecin :
Paramètres sonde(s) satisfaisant OUI / NON
Retour réglage habituel OUI/NON

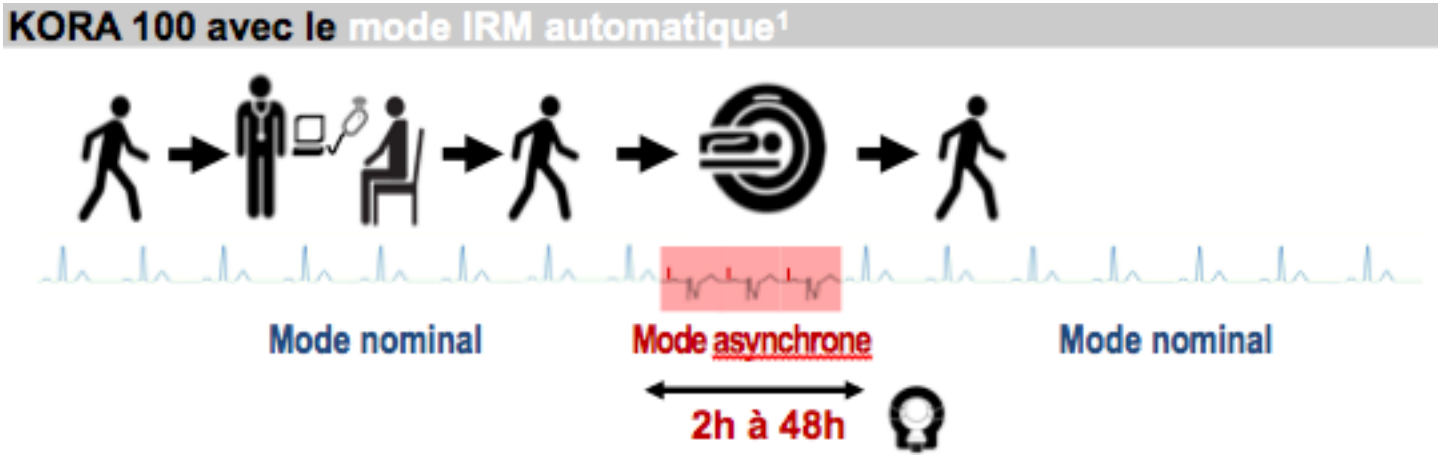
CHU

RAPPORT BENEFICE/RISQUE

SURVEILLANCE CLINIQUE PAR LE RADIOLOGUE

MODE IRM AUTOMATIQUE

SIMPLIFICATION DU CIRCUIT PATIENT



SYSTEME IRM CONDITIONNEL 3 TESLA

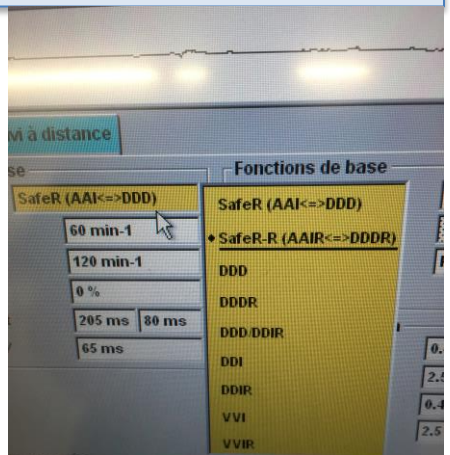
SIMPLIFICATION DE L'ACCES AUX EXAMENS NEURO

PMK "ACCOLADE" ET SONDES "INGEVITY" BOSTON
Disponible en 2015

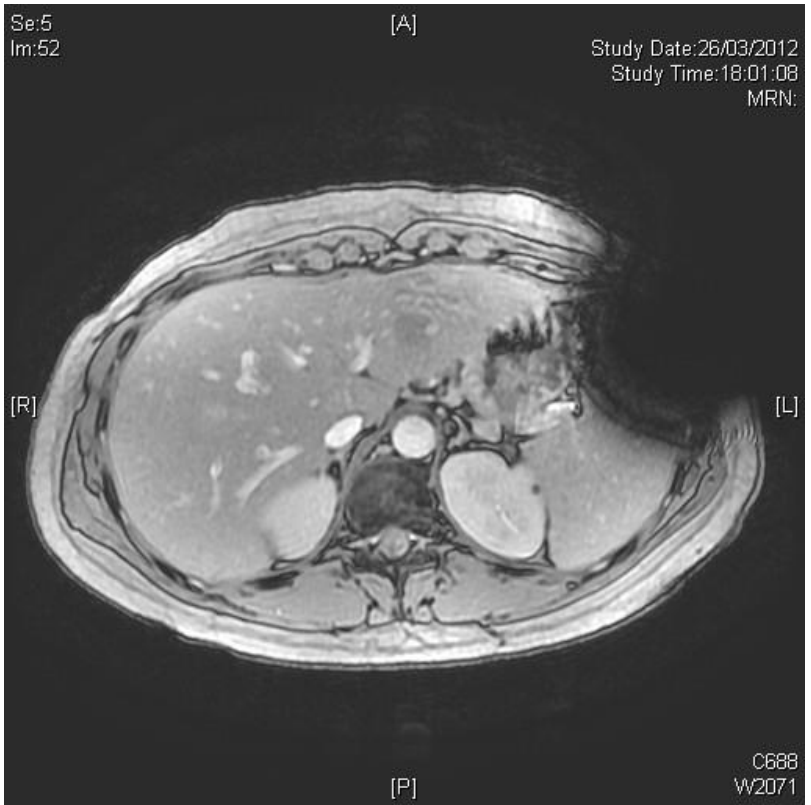
DAI ET IRM

2015 : 3 CONSTRUCTEURS IRM “COMPATIBLE”

INTERET : GARANTIE D’UN MODE ASYNCHRONE SI DEPENDANT



MONITEUR ECG



CONCLUSION IRM et PMK/DAI

“TOUS LES SYSTEMES SONT IRM CONDITIONNELS” !!

SYSTEMES CONVENTIONNELS : PAS UNE CONTRE INDICATION

SYSTEME “IRM COMPATIBLES “: FACILITENT LA GESTION

SUPERIORITE “IRM COMPATIBLES” : Thorax, 3T , DAI dépendant