Dispositivi Impiantabili Attivi RM Conditional: problematiche a confronto

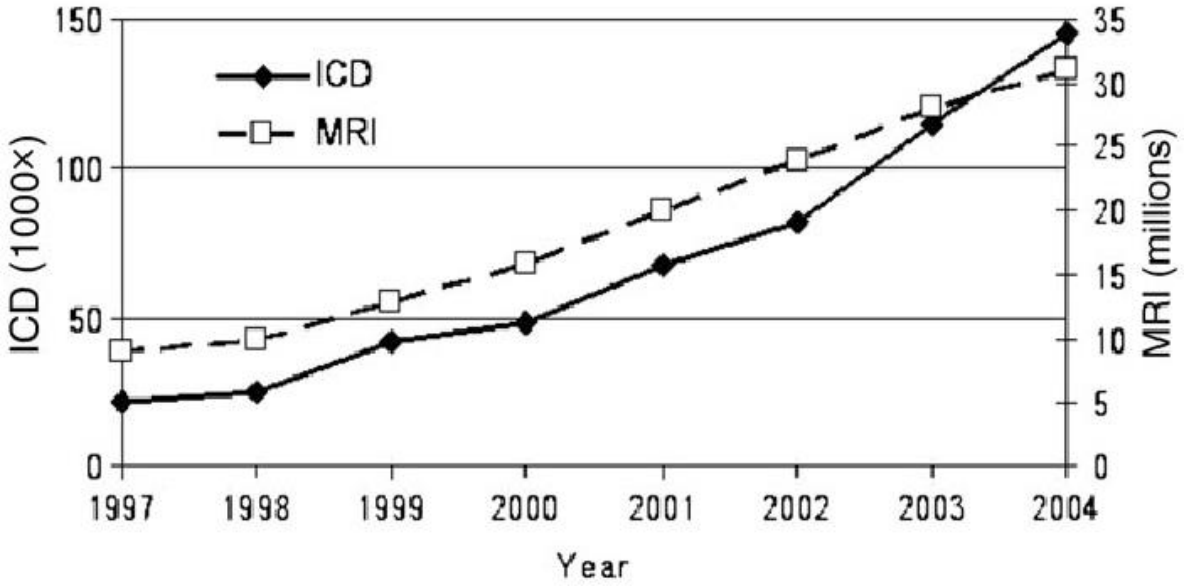
11 Dicembre 2015

Meeting Room
Nuovo Ospedale Sant'Agostino Estense di Modena

I Dispositivi Impiantabili Attivi RM Conditional nella pratica clinica.

Mauro Zennaro
U.O. Cardiologia

More than **2.000.000** patients in U.S.A had a permanent Pacemaker. Because the **advancing age** and **expanding indication** for **pacing** and **prophylaxis** of ventricular arrhythmia the number of patients with implantable cardiac devices will likely to increase



The combination results in an estimated **50-75% probability** of a patient being indicated for an MR study, creating an estimated **200.000** cardiac device patients who were denied MR scan

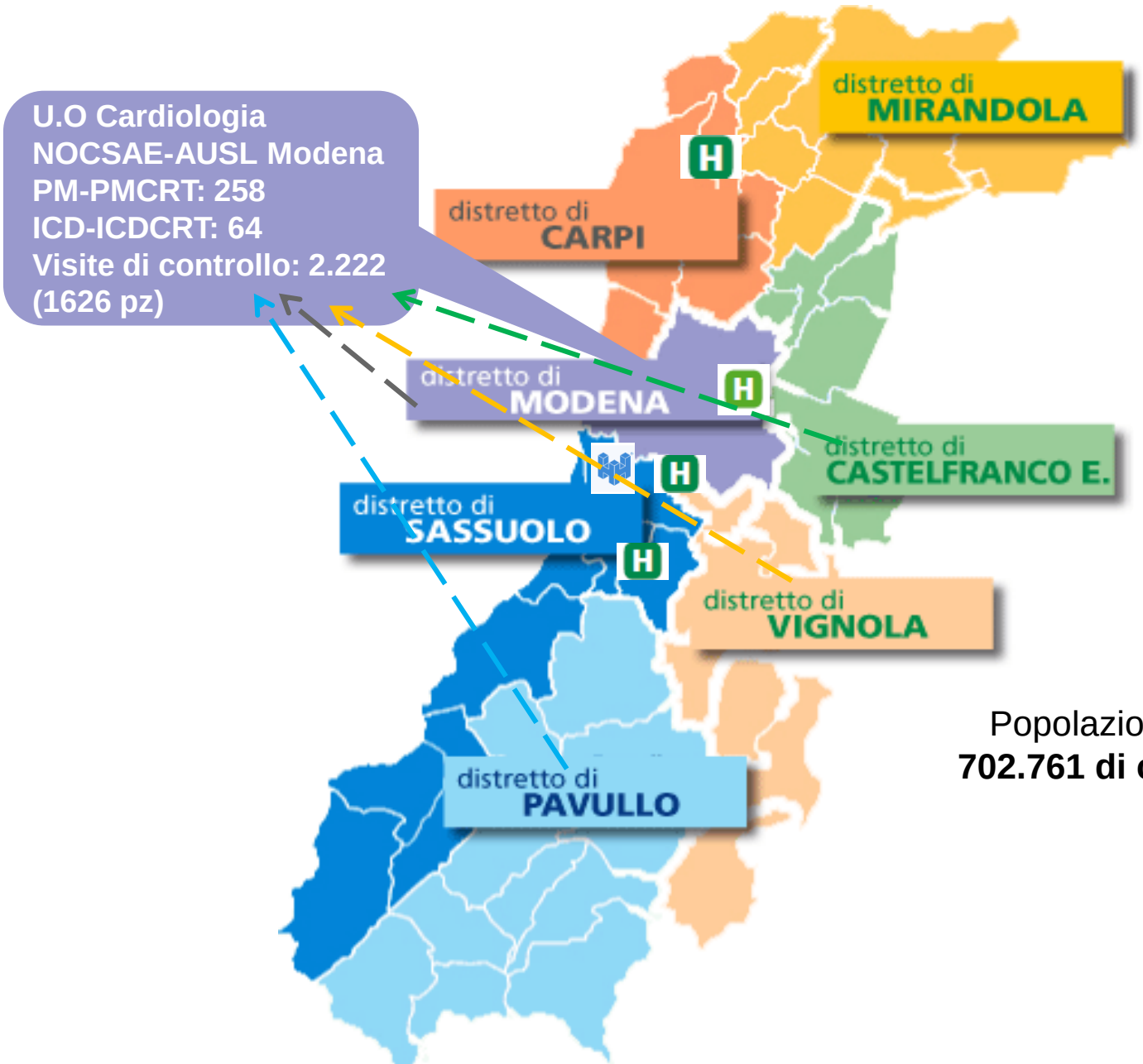
Brown DW. Am J Cardiol .2005;95:409-411

Kalin R Pacin Clin Electrophysiol 2005;28:326-8

Piramidi delle età della popolazione italiana tra il 1951 e il 2024

Istituto Nazionale di Statistica (ISTAT), "Previsioni demografiche dal 1.1.2007 al 1.1.2051" Giugno 2008

ATTIVITA' ELETTROFISIOLGIA 2014

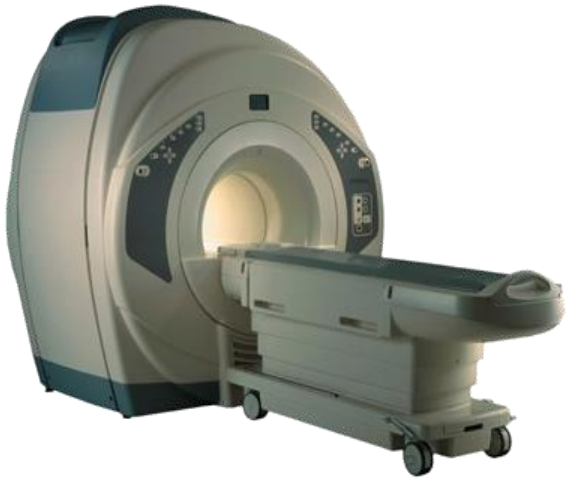


Popolazione Modena 2014
702.761 di cui 22% over 65aa

6 min	Every 6 minutes in europe an MRI scan is denied to a cardiac device patient*
17%	Patient required to undergo an MRI scan within 1 year from the implant**
50%-75%	Estimated probability that an MRI scan will be required to a cardiac device patient within the lifetime of the device**

* Gimbel JR. Europace. July 2010 - Gimbel JR. Pacing Clin Electrophysiol. June 2008 - Gimbel JR, Bailey SM, Tchou PJ, Ruggieri PM, Wilkoff BL. Pacing Clin Electrophysiol. October 2005 - Irnich W. Europace. July 2010

** Roguin et al., Europace, 2008,



MR safe An item that poses no Known hazards in any MR enviroment.

Non conducting, non magnetic, nonmetallic items

MR conditional An item demostrated to pose no known hazards in a specified MR imaging enviroment with specified condition use……

MR unsafe an item that in known to pose hazards in all MR enviroments

ASTM. http://www.astm.org

POSSIBILI COMPLICANZE

Static magnetic field
- Mechanical forces of ferromagnetic components (eg, pacemaker displacement)
- Unpredictable magnetic sensor activation
- Reed-switch closure and sudden loss of pacemaker function
- Changes in electrocardiograms

Gradient magnetic field
- Possible induction of serious arrhythmias (rare)
- Induced voltages on leads causing over- and/or undersensing

Modulated radiofrequency field
- Heating of cardiac tissue adjacent to lead electrodes
- Possible induction of serious arrhythmias (rare)
- Pacemaker reprogramming or power-on-reset
- RF interactions with the device (over- and undersensing)

Combined field effects
- Sudden and unexpected loss of device function
- Alteration of device function because of EMI
- Mechanical forces (vibration)
- Power-on-reset of the pacemaker or ICD pulse generator
- Damage to pacemaker or ICD pulse generator
- Damage to pacemaker or ICD lead(s)

Imaging-related
- Artifacts that prevent adequate image visualization

CHRS and CAR Consensus on MRI With CIEDs Canadian Journal of Cardiology 2014

POSSIBILI COMPLICANZE

Potential hazard	Mechanism	Solution
Lead heating, increased pacing threshold and potential loss of capture	RF energy dissipates through the lead tip, causing heating of the cardiac tissue	Extensive testing with multiple lead and device combinations and a variety of lead positions
Inappropriate pacing	▪ Over/undersensing ▪ Unintentional stimulation	▪ Specific MRI mode settings ▪ Dedicated testing performed to avoid inappropriate stimulation
Device malfunction	Hardware/software failure caused by strong forces	Specially selected, developed and tested materials, components and hybrid design

POSSIBILI COMPLICANZE

Batteria

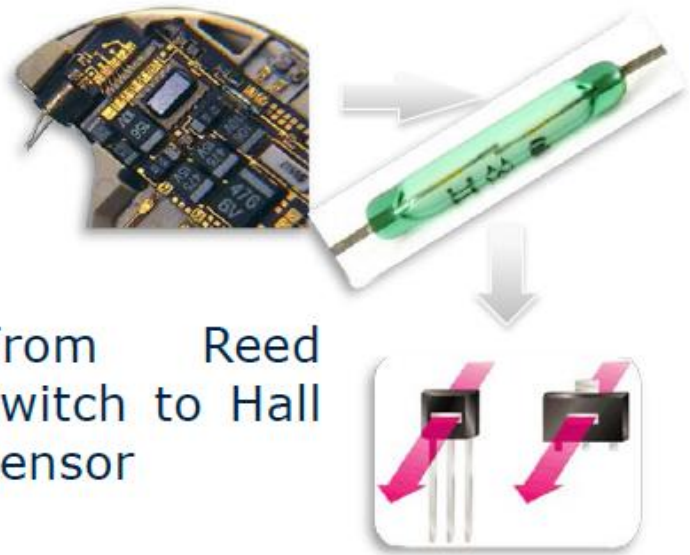
Negli anni da materiali ferromagnetici (nichel-cromo etc) si è giunti agli ioni di lito.

Cassa

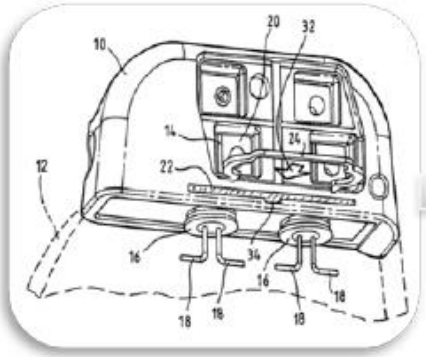
Il titanio è un materiale non magnetico che opportunamente trattato presenta una ridottissima permeabilità magnetica

Cateteri

Sono composti di una lega metallica MP35N (lega di nichel,cobalto cromo e molibdeno: =non ferromagnetici)



From Reed switch to Hall sensor



Feedthrough : protezione del circuito di alimentazione e della batteria

LE INCERTEZZE

Valhaus. 32 patients. 34 MR 0,5T. **Battery voltage decreased** and recovered. **Reed switch activation** is not predictable

Valhaus C. PACE 2001;24:489-95

Martin ET. 54 non-PM dependent. 64 MR 1.5T.9.4% **leads thresholds changes**

Martin ET.J.Am. Coll Cardiol 2004;43:1315-24

Schmiedel. 45 patients. 63 MR images 1.5T. All programmed asynchronous. Maximum SARS 1.2 W/Kg. **No complications**

Schmiedel et al Rofo 2005;177:731-44

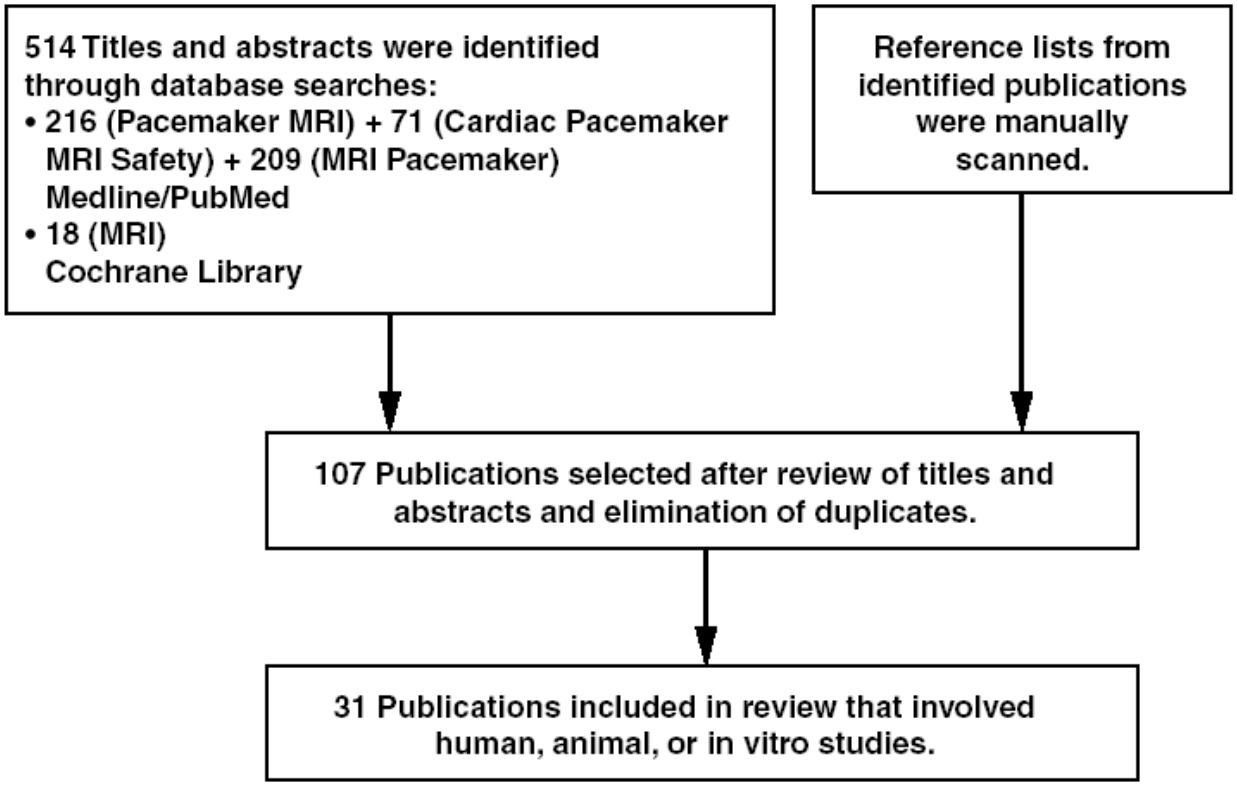
Sommer. 82 patients. 115 MR 1.5T. Single manufacturer. PM dependent excluded if thoracic region. SAR 1.5 W/Kg. **Pacing captured threshold increased** (p=0.017). 1 case cTnI increased

Sommer T. Circulation 2006;114:1285-92

Nazarian. 55 patients. 68 MR. 31 PM, 24 ICD. Average SAR<2.0W/Kg. Maximal capture change <1V. Diagnostic questions answered in 100% non-thoracic and **93% thoracic**

Nazarian S. Circulation 2006;114:1277-84

MRI of Patients With Cardiac Pacemakers: A Review of the Medical Literature



Joseph F.Zikria AJR:196,Febbruary 2011

15 Pubblication involved humans

1419 MRI examinations

In vivo studies concluded that MRI examinations affect pacemaker function, ECG readings, reed switch activity, symptoms and battery changes.

However, the clinical significance of the trials in this review was minor

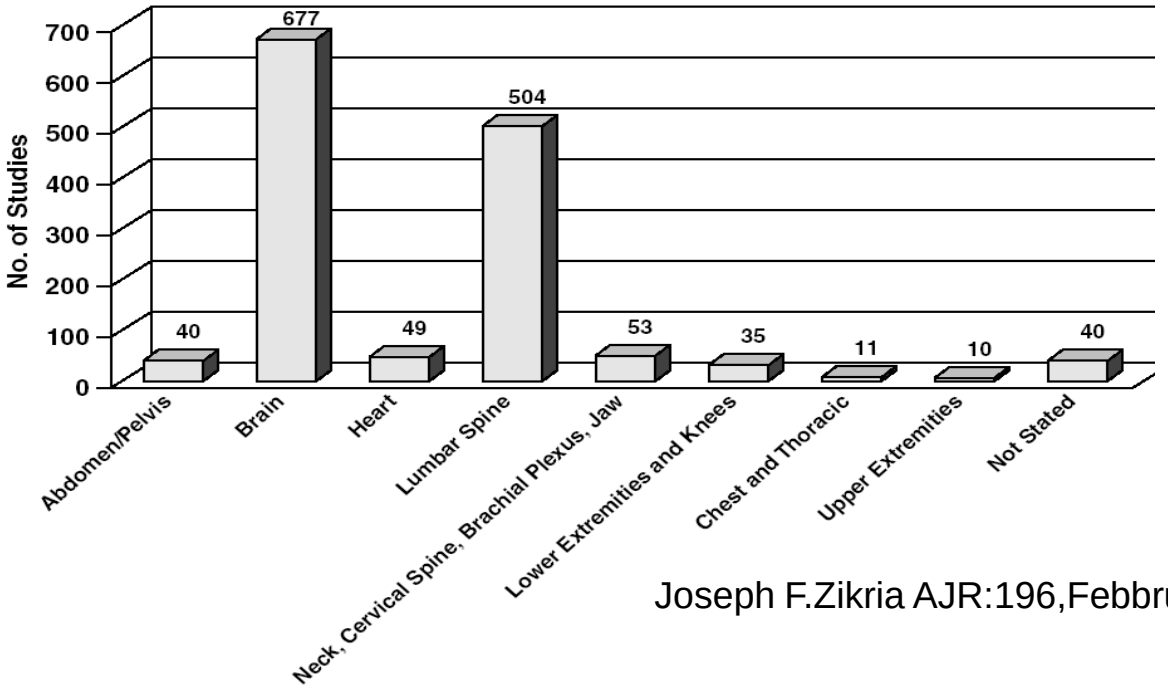
1 study 0.35T

4 studies 0.5T

8 studies 1.5T

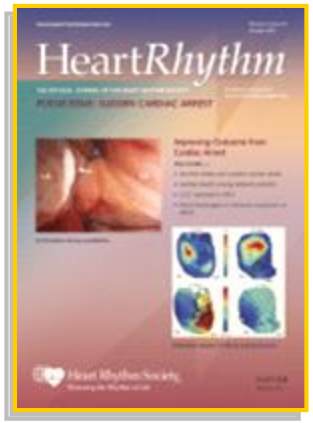
1 study 2.0T

2 study 3T



Joseph F.Zikria AJR:196,Febbruary 2011

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



OBJECTIVE:

The purpose of this prospective, randomized, controlled, worldwide clinical trial was to evaluate the safety and effectiveness of a **pacemaker system designed for safe use in MRI for any bradycardia indicated patient**

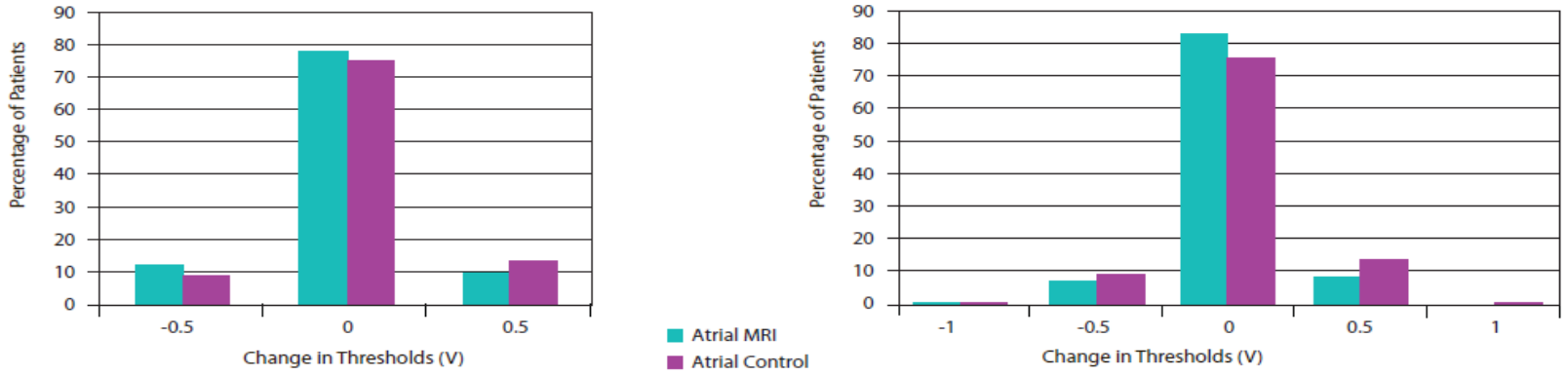
METHODS:

Patients (n = 464) were randomized to undergo an MRI scan between 9 and 12 weeks postimplant (MRI group, n = 258) or not to undergo MRI (control group, n = 206) after successful implantation of the specially designed dual-chamber pacemaker and leads

Willkoff, et al., Heart Rhythm Journal 2010

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



Willkoff, et al., Heart Rhythm Journal 2010

A Detailed View on Pacemaker Lead Parameters Remotely Transmitted after Magnetic Resonance

CHRISTIAN G. WOLLMANN, M.D.,*,†

A total of 2,428 data sets (mean 80 ± 20 per patient)

PMs were **interrogated immediately before and immediately after** MR to assess potential changes of lead parameters (right atrial, right ventricular, sensing [mV], PCT [V/0.4 ms], pacing impedance, as well as of battery status

-Patients were **followed for 3 months** with in-office visits at 1 month and 3 months after MR.
-Patients were **remotely monitored** using HM based on routinely scheduled 30-day or event triggered transmissions

This study is the first to report about remotely transmitted automatically implantable pulse generator (IPG)-based assessed lead parameters after MR.

No systematic (or clinically relevant) effects of MR on PM lead parameters could be found.

PACE 2015

American Heart Association
Learn and Live

Raccomendations for the Performance of MR Examinations in patients with Pacemakers or ICD

MR examinations of non pacemaker-dependent patients is discouraged and should only be consider in cases in witch there is a strong clinical indication and in witch the benefits clearly outweigh the risks

MR examination of pacemaker-dependent patients should not be performed unless there are highly compelling circumstances and when the benefits clearly outweigh the risks

MR examination of patients with ICDs should not be performed unless there are highly compelling circumstances and when the benefits clearly outweight the risks

American College of Radiology guidelines

the presence of implanted cardiac pacemekers should be considered a "relative controindication" for MRI and should be considered only in a case by case and site by site

Levine G.N. Circulation 2007;116:2878-2891
Kanal E.AJR 2007;188:1447-1474

Linee guida AIAC all'impianto di pacemaker, dispositivi per la resincronizzazione cardiaca, defibrillatori automatici e *loop recorder*

update 2011

AIAC
Associazione Italiana Aritmologia e Cardiostimolazione

2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

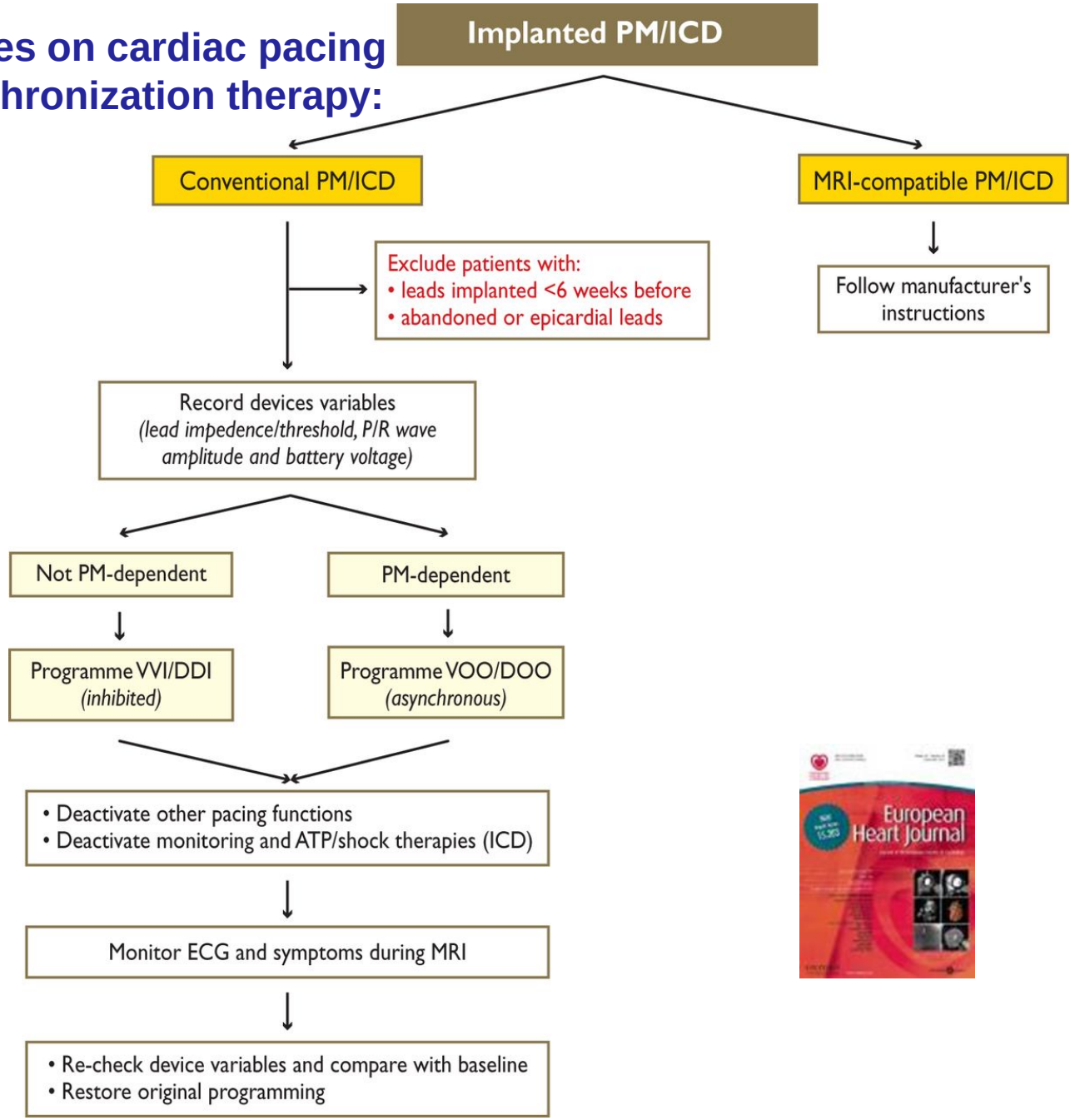
The Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA).

Europace (2013) **15**, 1070–1118

2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy:

Recommendations	Class [a]	Level [b]	Ref. [C]
1) Conventional cardiac devices. In patients with conventional cardiac devices, MR at 1.5 T can be performed with a low risk of complications if appropriate precautions are taken (see additional advice).	**IIb**	**B**	160–172
2) MR-conditional PM systems. In patients with MR-conditional PM systems, MR at 1.5 T can be done safely following manufacturer instructions.	**IIa**	**B**	173

2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy:



Report sondaggio sui device MRI conditional
Ottobre 2014

- Dalle risposte si evince un utilizzo relativamente frequente dei device MRI conditional, che vengono impiantati nell'81% dei centri, mentre solo il 19% non li ha ancora utilizzati. Relativamente alla scelta del paziente, il 52% ha risposto che li utilizzerebbe in tutti i pazienti ed il 46% solo in alcuni pazienti selezionati.

- Tra i Centri che hanno risposto, risulta già abbastanza diffusa la disponibilità di servizi diagnostici di riferimento con RMN ad altissima risoluzione (3 T), che sono presenti in percentuale del 45%. **Non è ancora abituale ma attuata nel 51% dei centri l'esecuzione di esami RMN nei pazienti portatori di defibrillatori MRI conditional**

AIAC
Associazione Italiana Aritmologia e Cardiostimolazione

RAPPORTI ISTISAN 15|9

ISSN: 1123-3117 (cartaceo) • 2384-8936 (online)

Dispositivi cardiaci impiantabili attivi e risonanza magnetica: aspetti tecnologici, inquadramento normativo e modelli organizzativi

I DEVICE

Feature	BOSTON	Medtronic	St. Jude	Biotronik	Sorin (H2 '13)
Full Body MRI	Y	Y	Y	Y (Only Safio)	Y
No limit on Scan time	Y	Y	Y	Y (Only Safio)	Y
SAR @ 1.5T (W/kg)	4	2	4	2	4
Automatic repro after scan	Y	NO	(activator)	NO	Y
DR and SR models	Y	NO	Y	Y	NO
Different price tier	Y	Y	NO	Y	NO
Using of existing leads	Y	Y	NO	NO	NO
Same handling lead	Y	Y	NO	Y	NO
Active and Passive Fixation	Y	Y	NO	N (Total body)	NO
Introducer size	6 Fr	7 Fr	8 Fr	7 Fr	7 Fr

I DEVICE

	BOSTON	BOSTON	Medtronic	St. Jude	Biotronik	Sorin Group
	INGEVITY	FINELINE II	CapSureFix MRI CapSure Sense	TENDRIL MRI	Safio / Solia	BeFlex
Fixation	Active (E/R helix) and Passive	Active (fix helix) and Passive	Active (E/R helix) and Passive	Active (E/R helix) and Passive	Active (E/R helix) and Passive	Active only (E/R helix)
Shape	Straight and J	Straight and J	Straight and J	Straight	Straight and J	Straight
Backward compatibility	NO	Yes	CapsureFix 5086 MRI Capsure Sense yes CapsureFix 5076 yes	NO	NO	YES
Lead Body Diameter	5,7 Fr	5,1 Fr	Min 5,3 Fr	6,6 Fr	5.6 Fr	6 Fr
Introducer Size	Min 6 Fr	Min 7 Fr	Min 7 Fr	Min 8 Fr	Min 6 Fr	Min 7 Fr
Estimated implanted Leads*	-	Fineline: 1’300’000	CapSure Sense: 420’000 CapSure Fix: 2.8 Mln	-	Setrox: 307’000 Siello: NA	-
Follow-up time*	-	> 11 yrs	10-12 yrs	-	Sentrox: 5 years	-

I DEVICE

	BSC	MDT	STJ	BIO
Full Body MRI Allowed	Yes – All combinations	Yes – All combinations	Yes – Pacing Off No [C1 to L2] – Pacing On	Yes – All combos above No – Other products and 3T
RV Leads	Active and Passive	Only Active	Only Active	Only Active
RA Leads	Active and Passive	Active and Passive	Only Active	Only Active
New or Existing	Existing	New	Existing	Existing
Magnetic Field	1.5T	1.5T	1.5T	1.5T (3T for other select products)
SAR (W/kg)	2.0 – All combinations	2.0 – All combinations	1.6 – 65cm 7122Q / LDA210 2.0 – 65cm 7120Q / LDA220 2.0 – 58cm all others listed	2.0 – All combinations
Tachy Therapy During Scan	No	No	No	No
Pacing Therapy During Scan	No	DOO / AOO / VOO	DOO / VOO	DOO / AOO / VOO
Auto Time Out	Yes – 3, 6, 12 hr or OFF	Yes – 6 hrs (fixed)	No Also, No SJM MRI Activator	No
Speaker Active After MRI	No	Yes	Yes	NA
Treshold Limit	NO	2,0v@0,4ms	2,5V@0,5ms	2,0V@0,4ms
Transmit/Receive coils limitation	R coil: no limit T-T/R coil: no on system directly	R coil: no limit T-T/R coil: no limit for limbs and head	R coil: no limit T-T/R coil: only head,upper extremity (wrist) and lower extremity (below hip)	R coil: no limit T-T/R coil: no torax

CONSIDERAZIONI

The long-term reliability and performance of MR-conditional devices are unknown.

Some MR-conditional leads are stiffer and larger than standard leads. In some reports, their use was associated with higher rates of dislodgment, repeated surgery, and perforation

MR-conditional CIEDs and leads are generally more expensive than traditional ones at the current moment.

CONSIDERAZIONI

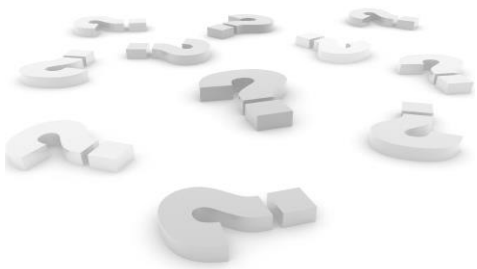
Other factors that might influence whether an Mr conditional CIED should be implanted include:

The patient's age, the presence of concomitant conditions, and the existence of known absolute contraindications to MR scanning.

Younger patients are more likely to require MR imaging at some point during their lifetimes.

If a patient has a concomitant disease (eg, malignancy) for which serial MR monitoring is required, an MR-conditional device should be strongly considered.

If a patient already has an absolute contraindication to MR scanning such as abandoned leads, CIED remnants, or other metallic prostheses (eg, mechanical valves, brain clips), then implantation of an Mr conditional CIED will be of little benefit.



Conventional Pacemaker

MR Conditional Pacemaker