

^dServicio de Cardiología, Hospital Osakidetza, Barakaldo, Biscay, Spain

^eServicio de Cardiología, Hospital Universitario de Getafe, Getafe, Madrid, Spain

^fServicio de Cardiología, Unidad de Rehabilitación Cardíaca, Hospital General Universitario Gregorio Marañón, Madrid, Spain

* Corresponding author:

E-mail address: pablotoledofrias@gmail.com (P. Toledo Frías).

Available online 17 January 2018

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<http://dx.doi.org/10.1016/j.rec.2017.10.046>

1885-5857/

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Selection of the Best of 2017 on the Usefulness of Cardiac Stimulation in the Treatment of Vasovagal Syncope



Selección de lo mejor del año 2017 sobre la utilidad de la estimulación cardíaca en el tratamiento del síncope vasovagal

To the Editor,

During 2016 and 2017, 5 papers have been published on recurrent vasovagal syncope with cardioinhibitory response to the tilt table test (TTT) and treatment with pacemaker implantation.

The first paper reported on a single center, retrospective, observational study of 24 patients with recurrent syncope. An in-depth diagnostic protocol was applied, including a TTT and exclusion of any other cause for syncope, followed by insertion of an implantable loop recorder (ILR). When patients then had a first syncope recurrence accompanied by asystole longer than 3 seconds or asystole longer than 6 seconds irrespective of syncope recurrence, they received a dual-chamber pacemaker with rate drop response (RDR). In the 35-month follow-up, syncope recurred in 7 patients, 4 of whom were TTT-positive. However, of the 17 patients without syncope recurrence, the TTT was positive in only 2.¹

The second paper described a prospective, multicenter study with 281 patients older than 40 years who underwent a diagnostic study starting with carotid sinus massage (CSM). Of these patients, 78 had asystole and were given an implantable PM. The remaining 203 patients underwent a TTT. A VASIS type 2B response with asystole was induced in 38 patients, who were then given an implantable PM. The remaining 165 patients received an ILR. Asystole was recorded in 21 of these patients, who were then given an implantable PM. All 137 patients treated with a PM received a dual-chamber device with rate drop sensing to allow minimal ventricular pacing time. Syncope recurred in 25 of the 281 patients (18%), and there were no differences according to the test (CSM, TTB or ILR) that indicated PM requirement. At 3 years of follow-up, 20% of the 137 patients with a PM had had syncope recurrence, which was significantly lower than the 43% in the 142 patients who received no PM ($P = .01$). Among the patients who had asystole during the TTT, syncope recurrence was 3% at 12 months and 17% at 21 months. Among the patients with a negative TTT, syncope recurrence was only 5% at 3 years.²

The third paper reported on a multicenter, prospective, single-blind, randomized study that enrolled 30 patients with a dual-chamber PM with closed-loop stimulation (CLS) implanted at least

6 months prior to enrolment, with a history of recurrent syncope and cardioinhibitory response to the TTT. At the initial visit, patients were randomized 1:1 by a central system into 1 of 2 pacing groups, DDD-CLS first or DDD first (at a fixed rate of 60 bpm), and they underwent a first TTT with the PM activated. At the end of the test, the PM was reprogrammed and 1 week later, the test was repeated with the other pacing mode, i.e., with crossover from DDD-CLS to DDD and from DDD to DDD-CLS. Compared with DDD, the DDD-CLS mode significantly reduced the occurrence of syncope in the TTT (30.0% vs 76.7%; $P < .001$). Among the patients who had a syncope in both TTTs and with both pacing modes, DDD-CLS significantly delayed the onset of syncope during TTT. The maximum fall in blood pressure recorded during the TTT was significantly lower in DDD-CLS than in DDD.³

The fourth paper described the SPAIN study, with a multicenter, prospective, randomized, double-blind design, that enrolled 54 patients with recurrent syncope and TTT cardioinhibitory response. A total of 46 patients completed the protocol. All patients received a DDD-CLS PM and were randomized 1:1 to 2 groups: group A first received DDD-CLS for 12 months and then DDI for 12 months; group B first received DDI and then DDD-CLS for the same periods of time as group A. During 22 months of follow-up, in group A, 72% of patients receiving DDD-CLS therapy had $\geq 50\%$ reduction in syncope versus 28% of patients receiving DDI; and in group B, all patients had $\geq 50\%$ reduction in syncope after switching from DDI mode to DDD-CLS in the second year ($P = .0003$). Just 4 patients (8.7%) had a syncope when in DDD-CLS mode, versus 21 (45.65%) who had one when in DDI mode (hazard ratio = 6.72; odds ratio = 0.11; $P < .0001$). The Kaplan-Meier analysis showed significantly longer time to first syncope in group A versus group B and the same finding was also observed in the 46 patients in DDD-CLS mode versus DDI mode ($P < .0001$). Therefore, DDD-CLS pacing significantly reduces syncope burden, lowers syncope recurrence 7-fold, and significantly prolongs time to first recurrence.^{4,5} The BIOSync study,⁶ the fifth paper referred to here, aims to confirm our results.

Gonzalo Barón-Esquivias,^{a,*} Carlos A. Morillo,^b Angel Moya-Mitjans,^c Jesús Martínez-Alday,^{d,e} Ricardo Ruiz-Granell,^f and Javier Lacunza-Ruiz^g

^aServicio de Cardiología y Cirugía Cardíaca, Hospital Universitario Virgen del Rocío, Universidad de Sevilla, Sevilla, Spain

^bDepartment of Cardiac Sciences, Libin Cardiovascular Institute of Alberta, University of Calgary and Population Health Research Institute-McMaster University, Hamilton, Canada

^cServicio de Cardiología, Hospital Universitario Vall d'Hebron, Barcelona, Spain

^dServicio de Cardiología, Hospital Universitario Basurto, Bilbao, Spain

^eServicio de Cardiología, Clínica IMQ Zorrotzaurre, Bilbao, Spain

^fServicio de Cardiología, Hospital Universitario Clínico de Valencia, Valencia, Spain

^gServicio de Cardiología, Hospital Universitario Virgen de la Arrixaca, El Palmar, Murcia, Spain

* Corresponding author.

E-mail address: gonzalo.baron.sspa@juntadeandalucia.es

(G. Barón-Esquivias).

Available online 13 February 2018

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Selection of the Best of 2017 on Cardiac Pacing: Magnetic Resonance in Patients With Pacemaker and Implantable Defibrillator



Selección de lo mejor del año 2017 en estimulación cardiaca: resonancia magnética en pacientes portadores de marcapasos y desfibriladores

To the Editor,

Magnetic resonance imaging (MRI) is the technique of choice for soft tissue characterization. Interest in performing MRIs in patients with a pacemaker (PM) or implantable cardioverter-defibrillator (ICD) has increased in the past few years. Despite being contraindicated until recently, it now appears unreasonable to deprive these patients of an investigation that will be indicated in an estimated 75% at some point during their life.^{1,2}

The 2013 European Society of Cardiology Guidelines on cardiac pacing and cardiac resynchronization therapy² has a flowchart with safety precautions for performing MRI in patients with conventional PMs and ICDs based on pooled evidence, and recommends following manufacturers' instructions for PMs and ICDs that are compatible with MRI (MR-conditional devices), which have been available since 2008. Systems labeled "MR-conditional" are those approved by competent authorities after demonstrating an acceptably low risk of complications when the generator and leads are tested together in a defined MR environment.

Some interesting articles have been published on this subject in the past year, 4 of which are of particular interest.

The MagnaSafe Registry³ was a prospective, multicenter study that analyzed the risk of performing nonthoracic MRI at 1.5 tesla for patients with conventional PMs (1000 patients, of whom 284 were pacing dependent) and ICDs (500 patients), excluding pacing-dependent patients with an ICD. No deaths, device failures, losses of capture, need for generator or lead replacement, or ventricular arrhythmias occurred during the MRI. A self-terminating atrial fibrillation episode was registered in 6 cases, and partial generator electrical reset was also observed in 6 cases. One ICD generator, which had not been appropriately programmed pre-MRI, required immediate replacement. Repeat MRI was not

associated with adverse events. An MRI was performed within 90 days of device implant in 46 patients with a PM and in 17 with an ICD. Clinical correlation between wave change variables and implantation time was not found.

Two consensus papers have reviewed publications to date. One was authored by the German cardiology and radiology societies,⁴ and the other was developed by the Heart Rhythm Society (HRS) in collaboration with 11 US, Japanese and European societies for arrhythmias, cardiology, oncology, and radiology.⁵ The authors of both papers conducted a detailed analysis of the physical and pathophysiological factors for the potential risks of MRI among patients with a PM or ICD, and they established highly specific MRI protocols to minimize existing risks. Both papers describe the responsibilities of cardiologists, radiologists and referring physicians in an MR procedure, stressing the need to adapt to individual cases, weighing up the risk-benefit, and being duly prepared to solve complications should they arise.

Unlike the European Guidelines, the German paper defines the presence of abandoned leads as a relative rather than an absolute contraindication in justified cases in nonpacing-dependent patients requiring nonthoracic MRI. The HRS consensus statement notes that pooled evidence is still insufficient in this respect and it contraindicates MRI in these cases. In view of the MagnaSafe Registry results,³ MRI can be performed in patients with recently implanted devices if clinically required.

Both papers stress that MRI is not risk free in patients with a PM or ICD, including MR-conditional devices, and patients should therefore be informed of these risks. Institutions should follow the expert recommendations and also adapt protocols to their own context.

In any case, it is always recommended to assess the following factors: need for the MRI, patient's electrophysiological risk (PM dependence, arrhythmic risk), type and condition of the device and leads (PM, ICD, MR-conditional, pacing and sensing thresholds, battery status, presence of abandoned, epicardial leads, etc.) pre-MRI interrogation/programming, MR system characteristics, monitoring during the MRI (continuous pulse oximetry, ECG), immediate post-MRI interrogation/programming, cardiopulmonary resuscitation equipment, expert personnel and device programmer present during MRI, and device check-up 3 months after the MRI.