

## About the Specialty Treating Patients With Heart Failure. Response



### Sobre la especialidad que trata a los pacientes con insuficiencia cardíaca. Respuesta

#### To the Editor,

We appreciate the interest shown by Dr Trullàs and Dr Miró in our study<sup>1</sup> and would like to address the questions that they raise in their letter.

The differences in the variables analyzed between the RICA and REDINSCOR registries are a reflection of normal clinical practice, in which the 2 specialties (internal medicine and cardiology) manage the care of distinct patient types. However, the validity of the comparative analysis between the 2 specialties lies first in the statistical matching method (propensity score), which provided more than 500 pairs of patients matched for up to 18 prognostic predictors that are widely contrasted in the medical literature and second in the fact that both registries are national, multicenter registries and the quality of their data is guaranteed by their respective scientific societies. In our study, we acknowledge that the lack of information on frailty and dependence in REDINSCOR prevented us from assessing the potential effects of these factors on our results.

Regarding the criteria for the definition of “optimal medical treatment”, we would like to clarify that we refer to the simultaneous prescription of beta-blockers plus angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers plus aldosterone receptor antagonists only in patients with a left ventricular ejection fraction  $\leq 35\%$ . We agree that the percentages obtained were very low. This may be partly explained by the lack of available data regarding reasons for not dispensing, as well as the fact that the inclusion periods for REDINSCOR and RICA began in 2007 and 2008, respectively, when the existing clinical practice guidelines<sup>2</sup> limited the indication for triple therapy to patients in the advanced New York Heart Association functional class.

Last, the reasons for the lack of statistically significant differences in readmission rates were beyond the scope of our analysis and warrant a targeted study. However, we would like to reiterate that an independent data collection committee validated the events during follow-up.

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## Role of Ivabradine in the Treatment of Heart Failure: Comments on the ESC 2016 Guidelines



### Papel de la ivabradina en el tratamiento de la insuficiencia cardíaca: comentarios a la guía ESC 2016

#### To the Editor,

We have read with interest the recent clinical practice guidelines for the diagnosis and treatment of heart failure (HF) by the European Society of Cardiology (ESC), published in Spanish in *Revista Española de Cardiología*,<sup>1</sup> as well as the comments on these guidelines by the expert group and Guidelines Committee of the Spanish Society of Cardiology.<sup>2</sup> First, we would like to praise the authors of this document for their deep and nuanced analysis of the ESC guidelines, which stresses their most important aspects and helps to clarify their most controversial recommendations.<sup>2</sup>

We would like to make some comments on the role of ivabradine in HF treatment and its consideration in the 2 documents. As noted by the authors of the Spanish Society of Cardiology document,<sup>2</sup> the recommendation for ivabradine use in patients with chronic HF and reduced ejection fraction has undergone subtle changes to more closely reflect the design and results of the study that informed the guidelines (SHIFT),<sup>3</sup> as well as its use in

patients unable to tolerate beta-blockers (IIb in 2012 and IIa C in the current 2016 guidelines<sup>1</sup>). Ivabradine is also listed as a second-line treatment, after beta-blockers, for patients with HF and angina pectoris in the “Comorbidities” section. However, in the translation published in *Revista Española de Cardiología*, made using the original English-language ahead of print version, there was a sentence on the doubts raised by the results of the SIGNIFY study<sup>4</sup> that said, “in the SIGNIFY study, in patients with limiting angina without HF, ivabradine increased the risk of cardiovascular death and nonfatal myocardial infarction, which is why it is not recommended in this context”. Although we agree with the conclusion of the cited article concerning patients with angina and without HF, we believe that this comment is not applicable to patients with HF and reduced ejection fraction because the SIGNIFY trial, in addition to using an ivabradine dose higher than that used for HF, excluded patients with HF, which could be a source of confusion in this matter. Indeed, this sentence has been removed from the latest corrected version of the ESC guidelines,<sup>5</sup> as well as from the translation of the guidelines.<sup>1</sup>

Finally, we would like to thank the authors of the Spanish document for having cited our article on the potential benefits of ivabradine administration during the hospitalization of patients with acute HF.<sup>6</sup> In our work, the first published study of this drug in the acute HF field, the combined use of ivabradine and beta-

blockers between 24 and 48 hours after patient admission for HF decompensation was as safe as the usual approach, namely, beta-blockers alone and use of ivabradine only in patients with heart rate > 70 bpm after maximum beta-blocker dose. The patients randomized to the ivabradine + beta-blocker group had a significantly lower heart rate 28 days after discharge, which was associated with a highly significant increase in ejection fraction at 4 months after discharge and a better functional class.<sup>6</sup> At 1-year follow-up, the left ventricular ejection fraction continued to be significantly higher in the patients who underwent early treatment with ivabradine during hospitalization. These data indicate the potential beneficial effects of this strategy for acute HF, which is of paramount importance given that no clinical trial has shown a favorable effect of any intervention (pharmacological or non-pharmacological) in this setting, as stated in the 2016 guidelines.<sup>1,2</sup>

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## Radiation Exposure to the Pregnant Interventional Cardiologist. Is It Really Necessary?



### Exposición de las cardiólogas intervencionistas a radiaciones ionizantes durante el embarazo. ¿Realmente es necesario?

#### To the Editor,

We read with great interest the article by Velázquez et al.<sup>1</sup> on radiation exposure in pregnant interventional cardiologists and we would like to congratulate the authors on their thoroughness. However, there are some issues that we would like to comment on.

First, the authors state that concern about ionizing radiation exposure during pregnancy can mean a 1-year interruption to the cardiologist's career. However, most cardiac catheterization and electrophysiology sections have more than one cardiologist,<sup>2,3</sup> and therefore in many cases the female worker can avoid exposure with a simple redistribution of tasks. This could, however, mean excess work load for the other members of the department unless maternity leave is covered by an interventional cardiologist. In addition, when the same department has 2 cardiologists who both wish to have children at a similar time, it may be (and often is the case) that they have to coordinate their pregnancies, although this is not always feasible for biological reasons.

Second, the authors assert that it is possible to work in the catheterization laboratory with a practically negligible risk if appropriate precautions are taken. We firmly defend the right of the workers to decide, rather than subjecting them to the dictates of Occupational Health and Safety, but we are concerned that there are no controlled clinical studies and that most of the data are extrapolated from animal studies. If we draw a parallel with drugs, most are not recommended during pregnancy because they have been tested only in animals, and the risk (however "negligible") is only accepted when there is a medical reason. However, in the case of workplace exposure to radiation, the risk is accepted with no

medical reason, which goes against the recommendations of Occupational Health and of the obstetrician, as well as the father's obvious reluctance. Furthermore, as the authors mentioned, the probability of spontaneous congenital malformation or childhood cancer is 4.07%. When this occurs, if the mother has been exposed to radiation, even if the dose received has been minimal and in theory the risk is negligible, it is likely that an explanation will be required, or demanded.

The article describes the protection used by exposed female workers. Two of them used additional material (1 of them up to 3 lead skirts), from which we can deduce that they did not feel safe with the standard protective equipment. Furthermore, it is often forgotten that pregnancy constitutes a situation of particular risk that predisposes to worsening of varicose syndromes and musculoskeletal problems due to the change in lumbar curvature and weight gain: use of skirts and vests (not to mention additional material) further aggravates this risk. We suggest that it would be preferable to invest in other protection methods, such as navigation systems, with which multiple substrate ablations can be performed without fluoroscopy,<sup>4</sup> and, above all, the use of complete protection screens (eg, hood-type) that are used in Europe, which avoid the need for vests and aprons and their associated problems.

Last, we wonder whether female interventional cardiologists feel completely free when deciding not to modify their activity during pregnancy. As we all know, working conditions have deteriorated in recent years and such decisions may be affected by the high rate of temporary contracts, up to 40% in the public health system.<sup>5</sup>

Therefore, until controlled studies in this setting are published, instead of burdening the female worker with the responsibility for this decision, we believe that it would be more appropriate to focus on adequately equipping laboratories with complete radiological protection methods, which in addition would benefit all exposed workers.