Revista Argentina de Cardiología
ISSN: 0034-7000
revista@sac.org.ar
Sociedad Argentina de Cardiología
Argentina

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Consensus on Atrial Fibrillation
Revista Argentina de Cardiología, vol. 83, núm. 4, agosto, 2015, pp. 360-361
Sociedad Argentina de Cardiología
Buenos Aires, Argentina

there are. A few years ago, the Research Area of the Argentine Society of Cardiology conducted a registry of the number of ICDs imported per year, surveyed by means of the customs registries. (11)

According to our registry, 1,058 ICDs were imported in 2007, resulting in a rate of 7.8 per million inhabitants, far below the 196 per million in USA and the 62.5 per million in Spain for that year.

One of the limitations of that registry was the difficulty in learning the type of indication, but the number was low compared with other countries.

In conclusion, the indication of devices for primary prevention is below of what it should be, resulting in preventable deaths.

There are structural causes that can hardly be changed, but there are also causes –unawareness, for example– which we must change. Each physician can have a critical view on the indications, but cannot be unaware of them. Our role is to disseminate the content of the guidelines and literature, so that all physicians can take the best decisions for their patients and improve the quality of health care.

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Rev Argent Cardiol 2015;83:359-360. http://dx.doi.org/10.7775/rac.v83.i4.6872

Consensus on Atrial Fibrillation

To the Director

It has been a great pleasure to receive the publication of the Consensus on Atrial Fibrillation of the Argentine Society of Cardiology. (1)

We would like to emphasize that, in line with the main guidelines and consensuses worldwide, the use of new anticoagulant drugs has been recommended at the same level as vitamin K antagonists.

In the description of new drug characteristics, dabigatran has been mentioned to be associated with higher rates of myocardial infarction compared with warfarin. It is important to clarify that such difference *was not statistically significant*. Regarding the RE-LY pivotal trial (2), which led to the approval of dabigatran for ischemic stroke prevention in patients with atrial fibrillation, a review of the events found in such trial had already been published in 2010, but was omitted in this consensus. (3)

This study revealed *low rates of myocardial infarction* both in the warfarin group (0.64% per year) as in the dabigatran groups (0.82% per year for the 110 mg dose group and 0.81% per year for the 150 mg dose group), with no statistically significant difference [dabigatran 110 mg vs warfarin (p=0.09); dabigatran 150 mg vs warfarin (p=0.12)]. (3) Clearly, the absolute difference in the rates of myocardial infarction was extremely low (~ 0.2% per year), limiting the statistical power to make comparisons. Such small numerical difference is even lower if only fatal myocardial infarctions are considered, with rates of 0.13%, 0.11% and 0.10% per year for dabigatran 110 mg and 150 mg, and warfarin, respectively. (4)

No less important, the rates of myocardial infarction observed in the RE-LY trial were consistent with those found in other trials on stroke prevention in patients with atrial fibrillation: between 0.53 and 1.4% per year both for warfarin and for different new oral anticoagulant drugs. (5)

Several studies and analyses on the topic were published after the consensus was written. In this regard, it is worth mentioning the findings of the RELY-ABLE study, which evaluated the safety of dabigatran during an additional follow-up of 2-3 years once the RE-LY study concluded. In that study, *rates of myocardial infarction continued to be low: 0.72%* per year for dabigatran 110 mg and 0.69% per year for dabigatran 150 mg, consistent with previous findings. (6)

In a comprehensive analysis, Clemens et al explains that the non-significant imbalance of the rate of myocardial infarction among patients on dabigatran (and considering the comparative nature of the measures of association) may result from the unusually low rate of myocardial infarction in the subgroup of

warfarin patients with some degree of valve disease: 0.3% per year, and very different from what is usually found in this population. (7)

More recently, Graham et al published an independent study for the FDA with more than 134,000 Medicare users >65 years of age, who initiated dabigatran or warfarin for treatment of atrial fibrillation. They were paired by propensity score. Compared with warfarin, dabigatran significantly reduced the risk of ischemic stroke (HR 0.80; 95% CI 0.67-0.96), intracranial hemorrhage (HR 0.34; 95% CI 0.26-0.46) and death (HR 0.86; 95% CI 0.77-0.96). *Once again, no significant differences were observed in the rates of myocardial infarction (HR 0.92; 95% CI 0.78-1.08).*

We would appreciate it if this clarification were published, so as to avoid misinterpretations among readers.

We congratulate the coordinators and authors of the consensus for their work and commitment in designing and disseminating local guidelines for all the physicians involved in the care of patients with atrial fibrillation.

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