

## Position Document on the Use of Direct Oral Anticoagulants in Nonvalvular Atrial Fibrillation

### *Documento de toma de posición sobre el uso de anticoagulantes orales directos en fibrilación auricular no valvular*

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The Argentine Society of Cardiology and the Argentine Federation of Cardiology have carried out a detailed analysis of the recent Ninth Health Technology Assessment Report by the National Commission for Health Technology Assessment (CONETEC) on the use of direct oral anticoagulants in nonvalvular atrial fibrillation. (1)

Atrial fibrillation (AF) represents 60% of the indications for anticoagulation in Argentina and worldwide. The view of AF reality in our country should take into account that AF is not systematically detected, anticoagulation is rarely performed, and when it is, the levels of time in therapeutic range (TTR) are inadequate, as we have verified in our records.

We believe that this assessment has its limitations: it was carried out under economic rather than healthcare criteria, which means that the conclusions drawn are not oriented towards the correct use of a valuable resource such as the new non-vitamin K-dependent direct oral anticoagulants (DOACs) and their positive impact on AF patients, but rather to their restrictive use due to their high cost, without counterbalancing aspects as the correct training of physicians in concepts such as the rational prescription of DOACs.

The analysis of the information in the report shows that 35% of patients with inadequate TTR from the TERRA registry, carried out in highly specialized institutions, were considered as data. That percentage does not reflect actual community practice, as it is estimated to be worse. However, economic estimates were based on these data.

Regarding the recommendation stating: “indication restricted only to patients treated with vitamin K antagonists who present abnormal INR values in >50% of the measurements”, it should be pointed out firstly that INR was not abnormal but out of range, and the percentage of visits should not be taken as a criterion. Instead, TTR, for which free computer tools are available, is much more appropriate. The indication should consider those who cannot meet adequate INR controls due to logistic constraints.

“Indication of treatment and renewal by a hematology specialist” is the recommendation that has

raised our greatest concern. Several observations should be mentioned:

1. AF is usually diagnosed and treated by a cardiologist.
2. The main documents on AF (by American and European guidelines) worldwide, in their anticoagulation sections, refer to the cardiologist as the recommended specialist to manage new oral anticoagulant agents.
3. The main risk scores for indicating anticoagulation are based on strictly cardiovascular parameters (heart failure, hypertension, vascular disease, etc.).
4. These new AF drugs are indicated exclusively in cardiac scenarios (ablation, cardioversion, angioplasty, acute coronary syndromes, etc.), which are the domain of our specialty.
5. Large randomized studies on these new oral anticoagulants were carried out with more than 95% of the patients included by cardiologists, demonstrating their expertise in the subject.
6. It is discriminatory, as it questions other specialists' ability to use it.
7. The indication for treatment and turnover should include Cardiology, Clinical Medicine, General practitioners and Neurology, as well as colleagues from other primary care specialties who could have this useful tool available for the prevention of embolic events and the reduction of complications associated with treatment, particularly in rural areas of our country.
8. It would be unfeasible for the thousands of patients already anticoagulated by cardiologists.
9. This recommendation is not based on any available evidence and is not established in any national or international clinical practice guideline.
10. Therefore, the indication for treatment and turnover by a specialist should include Cardiology, Clinical Medicine, General practitioners and Neurology. Policies establishing restrictions on drug prescription by specialty have failed due to the lack of specialists and because physicians are forced to prescribe them to the individual patient. For this reason, extensive training on the rational use of pharmacological

resources seems more appropriate than their mere prohibition.

In the case of hospitalized patients, clinicians and cardiologists have received extensive training, making it possible to promote hospital discharge by avoiding waiting 4 to 7 days for them to come into range, freeing up beds, or in the event of detection in the doctor's office, to have the patient anticoagulated in 12 hours and not in weeks of appointment delays in which the highest rate of embolisms occurs, which was neither considered in the economic analysis.

The lack of suitable laboratories and hemostasis specialists in large regions of Argentina and in many hospitals makes it necessary to consider, as in many other countries, that AF, with the appropriate algorithms, is a reason for consultation with general practitioners and cardiologists who can manage it. The number of clinicians and cardiologists in clinical practice is much higher than the number of hematologists. Preventing clinicians or cardiologists from prescribing anticoagulants in front of their patients, forcing referrals with

unavoidable delays, will not be ethically acceptable.

It should be pointed out that we are fully in favor of a "sensible DOACs price reduction".

In view of the above, our common position is that these recommendations should be reviewed prior to their final publication, given that their current version will not have the initially expected impact when this project was devised, neither for the health system nor for the patients.

#### **Conflicts of interest**

Alejandro Hershson, MD, and Eduardo R. Perna, MD, are President of the Argentine Society of Cardiology and of the Argentine Federation of Cardiology, respectively.

#### **Ethical considerations**

Not applicable.

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#### **REFERENCES**

1. <https://www.argentina.gob.ar/sites/default/files/informe09-nacos.pdf>