

of the INR.^{1–4} Crucially, these results are in accordance with those of international studies, including the decisive clinical trials of the direct anticoagulants. Recruitment of the investigators by convenience—rather than randomized—sampling could indeed cause a bias. However, the INR control is probably even worse than that found in these studies, because the investigators selected tend to be the most motivated and their results are thus likely to be significantly better than those of general clinical practice.

In addition, although Alfaro-Lara et al consider that terms like “patients with poor control” should be avoided, we believe that this term properly reflects the high-risk situation of many patients whose INR values are often outside the guideline-recommended therapeutic range.

Finally, the authors note that the results of the CHRONOS-TAO study¹ have also been calculated according to an “adjusted range” INR of 1.8 to 3.2, due to the possible margin of error of the coagulometer (± 0.2). We believe this statement to be incorrect because it could be misinterpreted. According to the authors, we understood that if a patient has an INR of 3.2, it is specifically because the error has been -0.2 , whereas if a patient has an INR of 1.8, the error has been $+0.2$. However, if the error is ± 0.2 , the INR interval to be reached would be 2.2 to 2.8. This approach would ensure an estimated INR control of 2.0 to 3.0, which is the appropriate range, as was first shown more than 10 years ago⁵ and as included in all clinical practice guidelines.

CONFLICTS OF INTEREST

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REFERENCES

- Alonso R, Figueroa CA, Mainar V, Arribas MP, Sánchez L, Rodríguez R, et al. Quality control of oral anticoagulant therapy in primary care in Madrid city, Spain: CHRONOS-TAO study. *Med Clin (Barc)*. 2015;145:192–7.
- Barrios V, Escobar C, Prieto L, Osorio G, Polo J, Lobos JM, et al. Control de la anticoagulación en pacientes con fibrilación auricular no valvular asistidos en atención primaria en España. *Estudio PAULA Rev Esp Cardiol*. 2015;68:769–76.
- Cinza-Sanjurjo S, Rey-Aldana D, Gestal-Pereira E, Calvo-Gómez C; en representación de los investigadores del estudio ANFAGAL. Evaluación del grado de anticoagulación de pacientes con fibrilación auricular en el ámbito de atención primaria de Galicia. *Rev Esp Cardiol*. 2015;68:753–60.
- Anguita M, Bertomeu V, Cequier A; en representación de los investigadores del estudio CALIFA. Calidad de la anticoagulación con antagonistas de la vitamina K en España: prevalencia de mal control y factores asociados. *Rev Esp Cardiol*. 2015;68:761–8.
- Hylek EM, Go AS, Chang Y, Jensvold NG, Henault LE, Selby JV, et al. Effect of intensity of oral anticoagulation on stroke severity and mortality in atrial fibrillation. *N Engl J Med*. 2003;349:1019–26.

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Degree of Anticoagulation Control in Patients With Atrial Fibrillation in Spain: Need to Minimize Biases and Contextualize Results. Response by Cinza Sanjurjo et al



Grado de control de la anticoagulación en pacientes con fibrilación auricular en España: necesidad de minimizar sesgos y contextualizar resultados. Respuesta de Cinza Sanjurjo et al

To the Editor,

First, we would like to thank Alfaro-Lara et al for their consideration of the study conducted by our group (ANFAGAL), and their acknowledgment of the effort made by the researchers regarding sample selection. However, we would like to go into certain aspects mentioned in their letter.

We are not in favor of broadening the therapeutic range of vitamin K antagonists. The only interval that is safe and is supported by evidence is between 2 and 3.¹ The failure to change the dose when a patient shows suboptimal control is referred to as “therapeutic inertia”, and under no circumstances should be used as an argument in a safety case.

With respect to self-monitoring, we wish to point out that it is not very widespread in Spain and that it is very costly. In fact, countries like Sweden that have reached extraordinarily high levels of control with the use of self-monitoring are modifying the management of oral anticoagulation in favor of a more extensive

use of direct oral anticoagulants, which are more beneficial in terms of costs and safety than said model.²

Regarding adherence to therapy, we completely agree, but would like to call attention to different publications and analyses resulting from key clinical trials,³ registries of data from real-world clinical practice,⁴ or cohort studies designed to examine this aspect,⁵ all of which appear to indicate that adherence is greater with direct oral anticoagulants.

It is the responsibility of prescribing physicians and primary care teams to carry out an adequate follow-up of patients receiving anticoagulation therapy, preferably in a program for chronically ill patients, to ensure the implementation of an integrated approach to risk factors, individual lifestyle, and adherence to the prescribed drugs.

Finally, the agreement among three studies is not due to the variables influencing the primary endpoint; rather, it comes about because, in different sample populations, the authors identify the similar percentage of patients with suboptimal control of anticoagulation.

Sergio Cinza Sanjurjo,^{a,*} Daniel Rey Aldana,^b Enrique Gestal Pereira,^a and Carlos Calvo Gómez,^c on behalf of the investigators of the ANFAGAL (ANTicoagulación en pacientes con Fibrilación Auricular en el ámbito de atención primaria de GALicia) study

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REFERENCES

1. Rose AJ, Hylek EM, Ozonoff A, Ash AS, Reisman JI, Berlowitz DR. Risk-adjusted percent time in therapeutic range as a quality indicator for outpatient oral

anticoagulation: results of the Veterans Affairs Study to Improve Anticoagulation (VARIA). *Circ Cardiovasc Qual Outcomes*. 2011;4:22–9.

2. Labaf A, Carlwe M, Svensson PJ. Efficacy and safety of novel oral anticoagulants in clinical practice: a report from three centers in Sweden. *Thromb J*. 2014;12:29.
3. Komócsi A. Discontinuation of anticoagulant treatment: from clinical trials to medication persistence. *Curr Med Res Opin*. 2015;31:1841–4.
4. McHorney CA, Crivera C, Laliberté F, Nelson WW, Germain G, Bookhart B, et al. Adherence to non-vitamin-K-antagonist oral anticoagulant medications based on the Pharmacy Quality Alliance measure. *Curr Med Res Opin*. 2015;31:2167–73.
5. Martinez C, Katholing A, Wallenhorst C, Freedman SB. Therapy persistence in newly diagnosed non-valvular atrial fibrillation treated with warfarin or NOAC. A cohort study. *Thromb Haemost*. 2015;114. <http://dx.doi.org/10.1160/TH15-04-0350>.

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