

COMMENTARY

We Base Primary Care Guidelines on Pragmatic Studies

María José Calvo

Primary Care Pharmaceutic. Área 4. Madrid. España.

The follow-up of anticoagulated patients has traditionally been considered difficult and their control has been exclusively carried out in hospital. In the last few years, in Spain, as well as in many other countries, the option of carrying out this control in primary care (PC) clinics has been established.

Some of the reasons used to justify this change in follow-up of anticoagulated patients has been the large growth in primary care and the increased professional training in this

health care setting, accompanied by the current safety of anticoagulant therapy due to the standardisation of medication by the prothrombin time (INR), and the recommended decreases in anticoagulant concentrations and, the subsequent lower frequency of haemorrhagic complications. Also, the increased number of indications in which oral anticoagulants are recommended leads to an increase in the number of patients who can be treated and, therefore, who need to be monitored periodically.

Key Points

- The computerised clinical history in primary care clinics makes it easier to carry out a proper follow-up of the medication of patients on treatment with anticoagulants and the easy detection of interactions and other problems associated with these drugs.
- The data obtained in studies designed to know which medications and what doses produce clinically significant interactions in patients cared for in primary care clinics should be the basis of the primary care recommended guidelines.
- The future of research in primary care will have no option but to jointly analyse the medical prescription data with the results in health to provide scientific evidence based on data of effectiveness which can re-direct clinical practice.

For the proper control of treatment with anticoagulants there needs to be coordinated health care between all members of the health team (doctors, nurses, and pharmacists) and a strict pharmacotherapeutic follow-up of these patients due to advanced age, the frequency of pharmacological interactions, and their clinical repercussions, the understanding of the treatment and its complications, the narrow therapeutic range, the variability in response.

This, together with the fact that mean age of these patients has also increased, that these patients receive multiple medications in many cases, and as, in general, their level of knowledge regarding their disease is very low, makes primary attention clinics the ideal place for patient follow-up due to the ease of access, the integrated care of the patient by means of the computerised clinical history present in many of the primary care clinics, and the capacity to give health education.

The article by Sánchez-Garrido et al¹ which is published in this issue of *ATENCIÓN PRIMARIA* describes the experience gained in the follow up of possible interactions in anticoagulated patients in a rural area and their possible haemorrhagic complications.

It is, then, the evaluation of the few studies carried out in primary care in this field, which enables us to find out about the interactions in real patients, under real conditions.

The patients included in the study are similar to the rest of the anticoagulated patients described in the medical literature, that is, with a mean age of 68 years and receiving multiple medications.^{2,3}

The total therapeutic act involves assessing the risk-benefit ratio that the drug carries, depending on the characteristics and condition of each patient.

Among these one has to take into account the concomitant use of drugs, since the incidence of adverse reactions increases 3-4 times on increasing the prescribed drugs from 1 to 6. The list of interactions with anticoagulants is endless, but they must be assessed individually and restricted to the clinically significant ones. For this reason, studies like this are necessary to help us to be aware of what happens in real situations and with real patients and provide us with real information on clinically significant interactions.

In this study, the authors refer to the use of pantoprazole and allopurinol and the presence of minor haemorrhages, and also indicate that this fact must be analysed in depth, since these patients have used other antiulcer drugs previously, and after the haemorrhagic episode took place it was decided to change to pantoprazole. This is an interesting line, mainly due to the fact that proton pump inhibitors are the drugs of choice in primary care and the information on their interactions is controversial, with little clinical significance and associated to the doses used. The use of pantoprazole is not low compared to the rest of the molecules of the group (according to notifications to the Food and Drug Administration).

To a large extent, the information available on interactions comes from clinical trials carried out on a small number of patients and in very controlled situations. This means we may come across controversial information associated with the clinical significance of the interaction. In the article the authors set out in detail the percentages of therapeutic groups not recommended for these patients due to having interactions.

Despite the fact that more than 50% of drugs belong to these groups, it has to be pointed out that 16.1% of patients had a minor haemorrhagic complication and no major haemorrhage was observed.

In the particular case of patients on treatment with oral anticoagulants, there are clinically relevant interactions and other less important ones, given the frequent monitoring of the INR carried out on these patients. This is one of the important points for reflection in this work: the search for drugs that theoretically interact with ease must not make us forget the need for exhaustive monitoring of these patients. The work entitled "Pharmacological interactions in patients treated with oral anticoagulants in a rural health area" represents a new contribution which adds to the knowledge of problems associated with medications.

To be aware which drugs and in what doses cause clinically significant interactions and base the recommendations in the primary care guides on data from pragmatic trials and not only on clinical trials, must be the future of research in primary care. A future increasingly more accessible and closer, due to the advances in computerisation which makes access to the clinical histories of patients attending health centres more straightforward and rapid.

The future of research in primary care will by necessity go on to analyse prescription data along with the health results to provide the scientific evidence based on data of effectiveness, that will enable clinical practice to adjust. The unresolved questions, such as what are the clinically significant interactions for those drugs and therapeutic groups where the marketing pressures sometimes do not let us know the reality, in what doses and in what patient profile, should be answered in studies carried out in the field of primary care.

References

1. Sánchez Garrido R, Molina Casado MP, Rodríguez Idígoras MI, Martínez González JL, Escolar Castellón JL. Interacciones farmacológicas en pacientes tratados con anticoagulantes orales en una zona de salud rural. *Aten Primaria*. 2006;38:427-34.
2. de Felipe Medina R. Nivel de conocimientos de los pacientes anticoagulados en un centro de salud; relación con el control terapéutico. *Aten Primaria*. 2003;32:101-5.
3. Guerra García MM. Diseño y evaluación de un programa de seguimiento farmacoterapéutico a pacientes anticoagulados en atención primaria de salud. *Revista FAP*. 2005;3:37-42.