Should NOACs Be Monitored Like Warfarin . . . and by Pharmacists?
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Drugs work only when patients take them. That seems simple, but it is a core issue with the so-called novel or new oral anticoagulants (NOACs), which I prefer to call the non–vitamin-K oral anticoagulants.

Warfarin adherence is easy to know. We measure its effect. Although this process increases the burden on patients, the advantages are obvious: patients interact with caregivers, get more opportunity for education, and all parties know whether the patient is taking the medicine. What's more, with warfarin, few caregivers go it alone. Most every doctor now recognizes the benefit of enrolling teams of people to help—as in anticoagulation clinics led by nurses or pharmacists.

NOACs, on the other hand, have been marketed and perceived as being more convenient—because monitoring is not necessary. A study just published in the *Journal of the American Medical Association* [1] (and reported by heartwire from Medscape) challenges that notion and provides data that may disrupt the entire framework of healthcare delivery of NOACs.

**The Study**

As background, the Stanford researchers previously showed [2] that adherence to dabigatran seen in clinical trials does not translate to the real world. They also knew NOAC adherence influences stroke outcomes. In the ROCKET AF [3] and ENGAGE-AF-TIMI 48 [4] clinical trials, both rivaroxaban (*Xarelto*, Bayer/Janssen Pharmaceuticals) and edoxaban (*Savaysa*, Daiichi-Sankyo) were superior to warfarin among patients who took the drug) but only noninferior in the intention-to-treat analysis (all patients).

The question for this current study was why and whether some of the variation in adherence was due to care delivery or infrastructure rather than the patient. The integrated VA system offers an opportunity to assess such site-level factors. Did some sites have patients who did well with adherence compared with other sites? And what were these sites doing differently? The research team did rigorous operations research, like a management consultant might do, and assessed the process of care at each site.

Site-specific factors that were assessed included:

**Appropriate selection.** Pharmacists carried out a detailed review of the patients' charts to ensure appropriate indication and rule-out contraindications and assess prior adherence to other medications.

**Education.** Pharmacists provided drug education before dispensing the drug to patients and reinforced this at subsequent visits.

**Monitoring.** Pharmacists led the monitoring of the patient. This included repeated assessment of adherence and adverse events as well as counseling on periprocedural stopping and starting.

Not all sites performed each of these steps. That variation allowed researchers to correlate adherence with site-specific processes.

**Results**

- Dabigatran adherence varied across the 67 sites, ranging from 42% to over 93% of patients adherent.
- The percentage of adherent patients was higher at sites performing appropriate selection (75% vs 69%).
education (76% vs 66%), and monitoring (77% vs 65%).

- After adjustment for variables, the practice of pharmacist-led appropriate indication assessment and adherence monitoring was associated with improved dabigatran adherence.

- Adherence increased with longer follow-up.

**Conclusions**

The authors concluded that among patients who filled dabigatran prescriptions within the VA system, there was variability in patient adherence across sites. Specific pharmacist-based activities improved patient adherence to the drug.

**Comments**

This is an important study on many levels.

It emphasizes the importance of NOAC-drug adherence. Everyone knows the vital role of adherence with warfarin, but it is less well-established with NOACs.

The convenience factor of NOACs increases the risk of distancing patients from their caregivers.

Anyone who prescribes NOACs worries about adherence, especially when these patients present for cardioversion or ablation. I often tell patients: "I can't [easily] know whether you are taking the pill. With warfarin, everyone knows, because we measure its effect. The only person who knows you are taking the NOAC is you." That is scary. Strokes are forever.

These results, therefore, challenge the notion that NOACs do not require warfarin-like monitoring. Adherence to dabigatran was strongly associated with pretherapy assessments and intensity and duration of monitoring—a novel finding.

Perhaps more disruptive to the status quo was that pharmacists improved care delivery. The reality of medical care in the US and other Western countries is that we are caring for sicker, older patients who take more and more medications. Pharmacology has always been important for clinical medicine, now more than ever. It makes perfect sense to enroll help with drug management and education.

**Three More Thoughts**

Can you see how this study hints at the future role of the physician? In days past, we did everything: diagnosed, prescribed, educated, and followed. That's no longer possible or wise. The future role of physicians will be to function as part of a team of caregivers rather than being the entire team.

I suspect these findings are just the beginning of a new chapter with NOACs. These investigators used drug adherence as an outcome measure; you could see how best care processes may translate to lower stroke and bleeding rates. I look forward to reading that team-based care of patients on NOACs saves lives.

Finally, to those who might consider VA care as inferior, this study reveals that regular citizens with AF would do well to get the sort of team-based care common in many VA hospitals.

JMM

**References**

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