MINDFUL PRACTICE

Anticoagulation Self-Monitoring

BY JON O. EBBERT, M.D., AND ERIC G. TANGALOS, M.D.

The Problem

A 54-year-old woman presents to you with difficulty maintaining a therapeutic international normalized ratio (INR). She has a history of ileojejunal bypass 17 years ago complicated by recurrent episodes of bacterial overgrowth requiring frequent courses of antibiotics. She also has antiphospholipid antibody syndrome with recurrent deep vein thromboses and pulmonary embolisms necessitating a Greenfield filter placement, which has been complicated by venous stasis syndrome. She frequently has difficulty maintaining her INR in the therapeutic range due to the need for antibiotic therapy, and she is frustrated. You both have noticed a strong correlation between subtherapeutic INR levels and pain and swelling in her lower extremities. She has searched the Internet and made contact with a company that manufactures a home INR monitoring device. She requests that you fill out a medical necessity form which is to be faxed to the company. This is your first experience with these devices, because until now the cost has been prohibitive for most patients. You wonder if these devices reduce bleeding complications and increase the amount of time patients spend in the therapeutic range.

The Question

Does self-monitoring of anticoagulation with Coumadin increase readings in the therapeutic range and decrease bleeding complications, compared with clinic-based, outpatient point-of-care monitoring?

The Search

You go to PubMed (www.pubmed.gov) and search "anticoagulation AND self-monitoring," limiting the search to randomized controlled trials. You see several RCTs and therefore limit the search to metaanalyses.

Our Critique

This review is of great help to clinicians trying to make sense of this exciting, emerging literature. However, it can be difficult to reach clear conclusions regarding outcomes because of potential differences between studies in the definitions of major and minor hemorrhage. Overall, the conclusions are favorable: Self-monitoring was associated with reductions in thromboembolic and major bleeding events; self-management was associated with reductions in thromboembolic events and death.

Patient Preferences & Clinical Decision

You decide that the patient is motivated and appropriate for self-monitoring. You complete the form and see if she can receive some financial assistance for the device.

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Self-monitoring of oral anticoagulation: a systematic review and meta-analysis. Review. Lancet 2006;367:404-11.

▶ **Criteria for Study Inclusion:** Published and unpublished controlled trials were included if they assigned patients randomly, compared the effects of self-testing or self-management of anticoagulation with control and dosage by a physician or anticoagulation management clinic, and/or reported clinical outcomes of thromboembolic and major bleeding events. Studies of both adults and children were included regardless of treatment indication with no language restrictions.

▶ **Study Identification:** EMBASE (1980-2005) and MEDLINE (1966-2005) were searched, limiting to randomized, controlled trials. The Cochrane Central Register of Controlled Trials and CINAHL (1982-2005) were also searched. Ongoing trials were identified using clinical trials registries, and experts in the field were contacted.

▶ **Study Selection:** All studies were assessed for methodological quality by three independent reviewers, and disagreements were resolved by discussion or by contacting authors.

▶ **Outcomes:** Primary outcomes were thromboembolic events, major bleeding episodes, death from all causes, and proportion of INR measurements within the therapeutic range. Secondary outcomes included testing frequency, minor bleeding events, and dropout rates.

▶ **Results:** The authors identified 14 randomized trials comparing self-monitoring with routine anticoagulation, with a total of 3,049 subjects. Patients were on anticoagulation for a variety of indications including mechanical valve (three studies), atrial fibrillation (two studies), and any indication (nine studies). Eight trials assessed the outcomes of self-management (self-monitoring and self-adjustment), and six assessed outcomes of self-monitoring only (no adjustment). Compared with controls, self-management and self-monitoring only decreased thromboembolic events (odds ratios 0.27 and 0.57, respectively; both groups combined, OR 0.45). However, among patients with mechanical valves, the effect on thromboembolic events was not significant (OR 0.60). For major hemorrhage, self-management did not reduce events, but self-monitoring only did (OR 0.56), compared with controls. For all-cause mortality, self-management reduced events (OR 0.37) but self-monitoring only did not, compared with controls. Eleven studies reported that the self-monitoring groups had improvements in mean INR results in the therapeutic range. Of the patients assigned to self-monitoring, 22% (range of 9%-43%) were unable to complete monitoring due to problems with the device, physical limitations, problems attending training, or failing the training assessment.

Standardization Urged in Valve Disease Guidelines

BY BRUCE K. DIXON
Chicago Bureau

CHICAGO — Newly issued guidelines seek to standardize valve surgery, improve the quantification of valve lesions, and involve patients in their management.

Released at a meeting sponsored by the American College of Cardiology, the Guidelines for the Management of Patients with Valvular Heart Disease recommend the widespread use of echocardiography and Doppler imaging, according the chairman of the guideline writing committee, Dr. Robert O. Bonow.

The 148-page document is the first revision of the practice guidelines of the ACC and the American Heart Association, originally released in 1998.

The guidelines are attempting 'to move the field into a more objective and quantitative approach.'

DR. BONOW

"What the guidelines are attempting to do is to move the field into a more objective and quantitative approach, and there are ways to do this with Doppler imaging, which many laboratories are not doing," said Dr. Bonow, chief of the division of cardiology at Northwestern University in Chicago.

"We do not want echocardiography and Doppler cardiograms being interpreted only qualitatively. If valve regurgitation appears to be severe, it should be measured so that the severity can be quantitatively demonstrated," he said in an interview.

Committee members who presented the guidelines at the meeting emphasized several issues:

▶ **Aortic stenosis.** The basic guidelines for aortic stenosis remain largely unchanged, but the revision clarifies the definition of "severe" asymptomatic aortic stenosis and states that adults with this diagnosis may be considered for valve replacement if there is a high likelihood of rapid progression or if surgery might be delayed at the time of symptom onset.

Also new is the recommendation that aortic valve replacement may be considered in patients undergoing coronary artery bypass grafting who have mild AS when there is evidence that progression may be rapid.

When valve replacement is considered, watchful waiting is advised, because there's no evidence in the literature that a benefit can be derived from performing valve replacement in the absence of symptoms, the new guidelines state.

▶ **Aortic regurgitation.** In recognition of the relatively benign course of lone asymptomatic aortic regurgitation, the committee recommended against valve repair or replacement in patients with normal left ventricular systolic function at rest. "Surgery is reasonable for patients with very large ventricles who may be at risk for sudden cardiac death," said committee member Dr. Patrick T. O'Gara.

Aortic valve repair or replacement also is indicated for symptomatic patients with severe aortic regurgitation irrespective of left-ventricular systolic function, and in those with severe AR who have a need to undergo cardiac or aortic surgery, explained Dr. O'Gara of the Harvard Medical School in Boston.

▶ **Mitral regurgitation.** Two themes emerge in the guidelines for mitral regurgitation, emphasizing the need for valve repair and earlier surgery. "The committee is trying to direct the trend more toward valve repair and away from valve replacement," said committee member Dr. Blase A. Carabello, vice chairman of the department of medicine at the Baylor College of Medicine in Houston, explaining that studies show that repair has survival advantages over replacement.

Another issue involves valve selection—mechanical or bioprosthetic—for those requiring replacement. The cutoff age of 65 for the use of bioprosthetic valves was liberalized to the advantage of younger patients who wish to avoid the use of blood-thinning drugs, Dr. Bonow explained. The patient should understand that, with a bioprosthetic valve, there's a high likelihood of the need for a second operation later on, he stressed.

The guidelines also clarify the use of blood thinners in pregnancy, recommending continuous anticoagulation in all pregnant women with mechanical prosthetic valves. Up to 36 weeks' gestation, the therapeutic choice of continuous dose-adjusted or intravenous subcutaneous unfractionated heparin, dose-adjusted low-molecular-weight heparin, or warfarin should be discussed fully. ■

The 2006 guidelines can be viewed online at www.acc.org and at www.myamericanheart.org.