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THINRS: Home INR monitoring as effective as clinic-based care

NOVEMBER 13, 2008 | Susan Jeffrey

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AAA **New Orleans, LA** – Results of a new randomized comparison shows that weekly home INR monitoring is safe but did not reduce stroke, major bleeds, or death when compared with monthly clinic-based INR testing.

Home monitoring did increase the amount of time spent in the target therapeutic range as well as patient satisfaction with anticoagulation therapy, the researchers note.

"We suggest that these results support that home INR testing is an acceptable alternative to high-quality anticoagulation management, such as in an anticoagulation clinic, and it may be preferable when patient access is difficult, such as might occur with patients with disabilities or [patients who live at a] geographic distance," **Dr David B Matchar** (Duke Center for Clinical Health Policy Research, Durham, NC), cochair of the trial, told a press conference here.

"Ultimately, the concern that we have is both access—that is, that people who are candidates for this extremely effective therapy receive the therapy—and quality—that is, that when they do receive the therapy, it's provided in the highest-quality way possible," Matchar concluded.

Results of **The Home INR Study (THINRS)** were presented here at the **American Heart Association 2008 Scientific Sessions**. **Dr Alan K Jacobson** (Loma Linda University School of Medicine, CA), study cochair, presented the THINRS results here during a late-breaking session.



Dr David B Matchar

Warfarin effective, but only if managed well

Warfarin is an effective therapy but only if managed well, Jacobson pointed out during his presentation. Warfarin is often underutilized, and the quality of management can be poor. Frequent home INR monitoring with weekly patient self-testing is a promising strategy to improve outcomes, he said, because it increases test frequency, which might allow more rapid identification and correction of out-of-target-range INRs, and promotes engagement of patients with their own care.

In this trial, the researchers compared these two strategies, weekly patient self-testing (PST), using an interactive voice-response reporting system and Web-based local monitoring, and currently recommended practice: high-quality anticoagulation management (HQACM), with testing carried out monthly at a clinic.

At the study outset, patients underwent training and confidence assessment to ensure their competence in using the home-based testing, Jacobson said. A total of 3644 patients with atrial fibrillation or mechanical valves were trained for the study, but only 2922 continued into the second comparison phase of the trial. For 80% of those not continuing, the issue was the time commitment to multiple evaluations and questionnaires, he noted.

As is not surprising for a VA population, participants were generally white, male, and somewhat younger than the typical anticoagulation population, he noted. The average warfarin dose was 5 mg/day with a relatively broad range, and 30% were on aspirin.

The primary end point was an aggregate of stroke, major bleeds, and death. Over an average of 54 months and 8370 patient-years of follow-up, there were 544 primary end-point events—237 deaths, 263 major

bleeds, and 44 strokes—but there was no statistical difference in the number of events between the intervention groups.

THINRS primary outcome: Risk of death, major bleeds, or stroke with home-based vs clinic INR testing

End point	Hazard ratio	95% CI	p
Time to first event	0.868	0.733–1.026	0.10

When they looked at total events, not just first events, between the two groups, there was a consistent trend toward benefit for PST on all three components of the primary end point, but none of the trends reached statistical significance, he noted. "Thus, while there was no evidence of patient harm with patients self-testing, we could not identify a benefit as large as the hypothesized 1.75% absolute reduction in total major events, even though the total number of events exceeded what was hypothesized," Jacobson said.

THINRS: Total events by intervention

Events	HQACM (%)	PST (%)
Stroke	0.76	0.69
Major bleed	4.46	3.85
Death	3.71	3.38
Total events	8.93	7.92

There was a 7% improvement in PST over HQACM in the time in target range that did reach statistical significance, and there was a slight progressive trend toward more improvement over time in the PST group. "Some feel that this may again represent the issue of patient empowerment and the ability of patients to begin to regulate lifestyle to further improve their anticoagulant control."

The Duke Anticoagulation Satisfaction Scale showed higher satisfaction with anticoagulation in the PST group, and the Health Utilities Index also demonstrated an improvement.

"We were impressed by the high proportion of patients who were able to competently demonstrate the ability to utilize PST either on their own or with the assistance of caregivers," Jacobson concluded. "These results support that home testing is an acceptable alternative to high-quality clinic care and may be preferable in those cases where patient access is difficult due to disability, distance, or other limitations."

Matchar noted that they are currently working on a cost-effectiveness calculation based on these results. "But it looks as if the costs are not going to be dramatically higher," he noted. "They might be nominally higher for the patient self-testing because there's the device cost and the strips, but it's not going to be dramatic."

I think it has the potential to expand the number of appropriate patients getting anticoagulated.

"Speaking just in terms of what it means for me clinically, I want to have as many options as I possibly can have to get the patients who should be anticoagulated treated and get them into a good range, and for some patients this will give me an opportunity that I wouldn't otherwise have, as long as I can get the system set up," Matchar said. "I think it has the potential to expand the number of appropriate patients getting anticoagulated."

Viable alternative approach



Dr Alan S Go

Dr Alan S Go (Kaiser Permanente of Northern California, Oakland) was the invited discussant for this trial. He noted that a previous meta-analysis of 14 smaller randomized trials had suggested a benefit from patient self-testing over various control strategies, but because of the wide variety of control approaches, there were concerns about the generalizability of those results. On this question, then, "THINRS makes an important contribution to our understanding," he said.

He pointed to a number of questions raised by these findings. For example, it was an unblinded trial by necessity, so there may have been other types of physician cointervention or behavioral changes in the groups, he said. In addition, high-quality anticoagulation services were required as a comparator with PST in this trial, "but many may not consider that part of the standard care in many practice settings in communities."

Finally, given the lack of difference in clinical outcomes and expenditure on the infrastructure required to provide access and coordination of services, patient self-testing may be a hurdle, he suggested

I believe that the THINRS results reinforce the

Still, he concluded, "I believe that the THINRS results reinforce the importance of delivering high-quality anticoagulation therapy regardless of the method and that this will lead to lower rates of

importance of delivering high-quality anticoagulation therapy regardless of the method.

ischemic stroke and intracranial hemorrhage as well as other adverse events."

In March 2008, Go added, **Medicare** expanded coverage for these devices to include patients with atrial fibrillation and venous thromboembolic disease. "Given the THINRS results, home INR testing with coordinated follow-up and close management appears to be a reasonable alternative to other types of structured care for appropriate patients with these conditions."

Dr Gordon F Tomaselli (Johns Hopkins University School of Medicine, Baltimore, MD), current chair of the American Heart Association Committee on Scientific Sessions Program, moderated the press conference here. He said the THINRS results will hopefully make "a relatively inexpensive and effective therapy even safer to use.

"I think many of us hoped that we wouldn't have to talk about warfarin anticoagulation, that there would be other options at this point, but there aren't," he added.

Not the standard of care?

During the press conference here, Matchar was asked about the issue Go touched upon, about whether this trial reflects how these patients are actually followed in the community.

In many cases, INR testing is done by off-site labs without point-of-care testing, and the coordination of how results are communicated first to the physician and then back to the patient is often suboptimal. Ideally, patients should get immediate feedback with this type of point-of-care device to minimize the risk of over- and undercoagulation and allow immediate correction of any problems. To compare patient self-care with a better standard of care than is often offered in the community is to potentially underestimate its benefit.

Matchar pointed out that the anticoagulation clinics participating in this trial still saw patients only once per month, and not all used point-of-care devices.

"So the high-quality anticoagulant management arm was basically what we believe can be achieved in general settings. That it's not achieved in general settings is a problem, but we should be able to do it, and certainly in the context of this trial, we felt it would be unethical to allow patients into an arm that we knew was substandard."

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