ATLANTA — Asking patients new questions on PAD alters Framingham Risk Assessment

WASHINGTON — Using validated functional performance measures is better than relying on patient reporting to determine walking ability and the effects of treatments in peripheral arterial disease, according to Dr. Mary McGrae McDermott of the Department of Medicine at Northwestern University, Chicago.

Each measure has positives and negatives, said Dr. McDermott, the lead investigator in the Walking and Leg Circulation Study (WALCS). That study used several performance measures of walking and leg function, including the 6-minute walk test, repeated chair stands, a standing balance test, and a test of walking speed (Ann. Intern. Med. 2002;136:1-32).

One of the most often-used performance measures is the treadmill walking test, but some data suggest it might not mimic actual walking, Dr. McDermott said. And older patients may experience anxiety or balance problems that have an impact on results, she said. A 6-minute walk test conducted in a corridor may be easier and more productive for older patients, according to Dr. McDermott. The test should be done in a 100-foot-long hallway, with patients told to walk as far as they can during the 6 minutes, with no conversation during the test.

The 6-minute walk test was shown to be reliable in a 1998 study (J. Amer. Geriatr. Soc. 1998;46:706-11). Dr. McDermott and her colleagues have completed a study, which has been submitted for publication, showing that 6-minute walk performance at baseline predicts mortality. In addition to the 6-minute walk, clinicians should consider other tests that measure leg strength, balance, and walking speed.

Together, these additional diagnostics constitute the summary performance score (SPS). Each score is based on a 0-4 scale and is added to create a total score of 0-12.

The first component is the 4-meter walk test, which is conducted in a corridor with a stopwatch. Dr. McDermott has found that patients who do not walk regularly for exercise have the greatest decline in the 4-meter speed. The SPS also includes a standing balance test and time to arise five times consecutively from a seated position. Lower SPS scores are associated with a higher risk of death, nursing home placement, and a reduction in the ability to perform activities of daily living, she said.

Physical activity can be measured with a vertical accelerometer, said Dr. McDermott, who discussed recent validation studies of the Caltrac version (Muscle Dynamics Fitness Network).

In the trials, PAD patients were given the toe-reel device to wear for 7 days, except when sleeping or bathing. Dr. McDermott and her colleagues found that PAD patients had much lower activity than non-PAD patients, and that the performance correlated with 6-minute walk test results (J. Amer. Geriatr. Soc. 2001;49:747-54).

New Questions on PAD Alter Framingham Risk Assessment

BY BRUCE JANCIN
Denver Bureau

ATLANTA — Asking patients two brief questions about self-reported peripheral artery disease, as a supplement to the standard Framingham cardiovascular risk assessment, results in reclassification of a substantial proportion of patients as being at high rather than intermediate risk, Dr. Maya J. Salameh reported at the annual meeting of the American College of Cardiology.

The two yes/no questions are: Do you get pain in the back of your legs when you walk? Have you been told you have vascular disease in the legs?

Participants in the Northern Manhattan Study who answered yes to one or both questions were found to have a greater incidence of major vascular events, compared with patients in the same Framingham risk score category who answered in the negative, said Dr. Salameh of Columbia University, New York.

Among 5,083 participants with no baseline history of major vascular events, the prevalence of self-reported peripheral artery disease (PAD) as defined by an affirmative answer to one or both of the questions on the intake questionnaire was 15%.

During a mean follow-up of 5.5 years, there were 397 major vascular events, defined as MI, ischemic stroke, or vascular death. Among individuals with a low Framingham risk score, meaning their calculated 10-year risk of a cardiovascular event was less than 10%, the actual 5-year cumulative rate of major vascular events was 4.1% in participants without self-reported PAD and a nearly identical 4.2% in those with self-reported PAD.

But 5-year vascular event rates were higher in those individuals with an intermediate Framingham risk score who had self-reported PAD than in those who didn’t (11.7% vs. 8.7%). And the disparity in event rates between those with and without self-reported PAD was even greater in those in the high-risk Framingham category (29.1% vs. 17.1%), which is reserved for those whose Framingham score places them at an estimated 10-year risk in excess of 20%.

Extrapolating from the Northern Manhattan Study 5-year results, the estimated 10-year vascular event rates in individuals without self-reported PAD who were in the low-, intermediate-, and high-risk Framingham categories at baseline were 8.2%, 17.4%, and 34.2%, respectively, which is consistent with how the risk is supposed to be distributed.

Patients with self-reported PAD, however, were another story. Their extrapolated 10-year vascular event rates were 8.4%, 23.4%, and 58.2% for individuals in the low-, intermediate-, and high-risk Framingham categories.

The 10-year major vascular event rate of 23.4% in the intermediate-risk group means those individuals actually belong in the high-risk Framingham category, Dr. Salameh said.

Statins Reduced Vascular Events In Peripheral Arterial Disease

BY MITCHEL L. ZOLER
Philadelphia Bureau

PHILADELPHIA — Statin use cut the incidence of major vascular events in patients with peripheral arterial disease in a subanalysis of results from the Heart Protection Study.

The results show that “all patients with peripheral arterial disease [PAD] should be on a statin regardless of their baseline lipid level,” Dr. Richard Bulbula said at the Vascular Annual Meeting.

“This is probably the first study to show the benefit of statin treatment in a predominantly PAD group [These are] very important data,” commented Dr. Thomas F. Lindsay, director of the vascular center at Toronto General Hospital.

The study used data collected in the Heart Protection Study, a British trial with more than 20,000 patients that compared treatment with 40 mg of simvastatin daily with placebo (Lancet 2002; 360:7-22). The total group included patients with coronary disease, other occlusive arterial disease, or diabetes. In the overall study, treatment with the statin was linked to a relative cut in deaths of 13% and lowered major vascular events by 24% during 5 years of follow-up.

The new analysis focused on the 6,748 patients who entered the study with documented PAD. This subgroup included patients with coincident coronary disease, coincident cerebrovascular disease, coincident diabetes, and more than 1,400 patients who had PAD as their only pre-existing disorder.

During 5 years of follow-up of the entire PAD subgroup, the rate of major vascular events (coronary death, nonfatal myocardial infarction, stroke, or revascularization) was 26% in the statin-treated group and 33% in the placebo group, a statistically significant difference, reported Dr. Bulbula, a researcher with the clinical trial service unit of the University of Oxford (England).

The degree of event reduction from statin therapy in this subgroup was very similar to what was seen in the entire study and in the subset of patients who did not have PAD at entry.

Statin treatment led to a significant reduction in vascular events regardless of whether patients started with a serum level of low density lipoprotein (LDL) cholesterol above or below 116 mg/dl.

These results also probably underestimated the impact of simvastatin treatment because some patients in the statin group stopped taking their drugs, and some in the placebo group eventually started on a statin, Dr. Bulbula said. Another analysis of the data, using the entire study group, looked at the ability of statin treatment to cut the incidence of major peripheral vascular events. These were defined as noncoronary revascularizations, aneurysm repair, major amputations, or deaths due to PAD.

These events occurred in 4.7% of the statin-treated patients and in 5.5% of those on placebo, a statistically significant difference. The impact of statin therapy on reducing peripheral vascular events has not been previously reported in any other statin-treatment study. Dr. Bulbula said. This effect by simvastatin treatment was primarily driven by a lower rate of peripheral revascularization procedures.

These results, along with other recent findings on statin therapy, suggest that the lower the level of LDL cholesterol in patients with PAD the better.