from this study. Acute heart failure subsequently was diagnosed in 568 of these patients, and 1073 patients had non-acute heart failure.

The primary endpoint of the trial was the comparison of the ability of MR-proADM and BNP to predict 90-day mortality. The researchers also evaluated the predictive value for MR-proADM and NT-proBNP, additive predictive value, and prognostic ability among all patients who were evaluated for dyspnea.

Stefan D. Anker, MD, PhD, Campus Virchow-Klinkum, Charite Medical Center, Berlin, Germany, co-principal investigator of the study, reported that the MR-proADM test had better prognostic accuracy for 90-day mortality than BNP (73.5% vs 60.8%; p<0.001). The novel biomarker also was significantly superior to NT-proBNP in predicting death within 90 days (73.5% vs 63.6%; p<0.001). The prognostic power of MR-proADM was even stronger for 30-day than for 90-day mortality (area under the curve [AUC], 0.739 vs 0.674). The corresponding AUC values were 0.555 versus 0.606 for BNP and 0.641 versus 0.664 for NT-proBNP.

Dr. Anker noted that the prognostic accuracy for 90-day mortality was improved by adding MR-proADM to BNP (chi^2 statistic 23.9; p<0.0001) or to NT-proBNP (chi^2 statistic 15.3; p<0.0001). In contrast, adding either BNP or NT-proBNP to MR-proADM did not increase the prognostic value (p=0.906 and p=0.291, respectively).

The MR-proADM test was also evaluated in terms of prognosis among all patients in the study who had visited the emergency room due to dyspnea. The prognostic accuracy of MR-proADM was significantly better than BNP or NT-proBNP (chi^2 statistic 129.5 for log MR-proADM vs 60.1 for log BNP and 83.7 for log NT-proBNP; p<0.0001). Dr. Anker pointed out that the prognostic ability of MR-proADM was in fact better among patients who did not have acute heart failure than among those who did (interaction p=0.005).

The better prognostic ability of MR-proADM makes it a superior risk stratification tool, which can help lead to better patient management, said Dr. Anker. However, because the 90-day mortality is high for all patients with heart failure, the biomarker actually distinguishes patients who are at very high risk from those who are at high risk. This fact, coupled with the lack of different treatment options for patients who are at very high risk of death after heart failure, makes it unclear whether the biomarker has true clinical utility.

Home Anticoagulation Monitoring is Safe for Patients with Atrial Fibrillation or Mechanical Heart Valves

For patients who are chronically taking the blood thinner warfarin, weekly home monitoring of the international normalized ratio (INR) is a safe alternative to monthly clinical monitoring, according to new results of The Home INR Study (THINRS; NCT00032591). Although more frequent home monitoring did not improve clinical outcomes compared with regular on-site clinic testing, the safety findings support its use, particularly among patients whose disabilities or geographic distance may limit access to a clinical lab for anticoagulation monitoring.

Warfarin is an effective therapy if it is managed well, which means maximizing the time that is spent at a therapeutic INR (range, 2.0-3.0) or time in the target range (TTR). When the intensity of anticoagulation exceeds the upper INR target, patients are at an increased risk for intracranial and other bleeding; when the anticoagulation intensity is below the INR target, the risk for ischemic stroke rises sharply. Therefore, carefully managed warfarin therapy can optimize the benefit of warfarin for prevention of thromboembolism. In the Anticoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study, a greater proportion of TTR was associated with a greater net clinical benefit – a composite of the number of thromboembolic events that is prevented by warfarin therapy minus the number of intracranial bleeds that is attributed to anticoagulation [Go AS American Heart Association Scientific Sessions 2007. Abstract 3590].

The goal of the THINRS trial was to assess whether increasing test frequency via home monitoring could further enhance the benefit of warfarin in patients who require chronic anticoagulation. Alan K. Jacobson, MD, Loma Linda University School of Medicine, Loma Linda, CA, presented results from THINRS at the American Heart Association Scientific Sessions meeting in New Orleans.

In THINRS, 2922 anticoagulated patients were randomly assigned to weekly home INR testing or monthly clinical monitoring. Prior to randomization, all patients received training on the home monitoring system and demonstrated proficiency following the testing protocol. All patients were taking warfarin to reduce the risk of thromboembolism that was related to atrial fibrillation or mechanical heart valves.

After a mean follow-up of 3 years, 7.9% of patients in the home monitoring group and 8.9% of those who were undergoing clinical testing reached the primary composite endpoint of ischemic stroke, major bleeding, or death. Although time to first major event trended in favor of home monitoring, the benefit was not statistically significant (HR, 0.87; 95% CI, 0.73 to 1.03; p=0.10).

According to an analysis of secondary endpoints, home monitoring modestly improved the total TTR compared with clinic monitoring (70% vs 62%). Home INR monitoring also improved patient satisfaction with anticoagulation treatment, as measured by the Duke Anticoagulation Satisfaction Score (47 vs 49).

Alan S. Go, MD, Kaiser Permanente of Northern California and University of California, San Francisco, CA, questioned whether THINRS was underpowered to demonstrate a reduction in the most relevant outcomes of ischemic stroke and intracranial bleeding with home monitoring compared with clinic INR testing but noted that the absolute number of ischemic strokes or intracranial bleeds was essentially the same in both treatment arms. Due to effective anticoagulation – as shown by a cumulative TTR of >62% in both study arms – patients had very low event rates. THINRS reinforces the importance that high-quality anticoagulation, regardless of the method of monitoring, leads to low rates of ischemic stroke and intracranial bleeding, he said.

"Home INR monitoring with coordinated follow-up is a reasonable alternative for appropriate patients with mechanical valves, atrial fibrillation, and venous thromboembolism," Dr. Go concluded. Additional secondary outcomes from THINRS, including other clinical events, compliance with self-testing, quality of life, and cost-effectiveness, will be reported in future presentations.

No Significant Benefit With Rosiglitazone In Preventing Progression of Atherosclerosis In Diabetic Patients With a History of Cardiovascular Disease

Results of the APPROACH trial (Assessment on the Prevention of Progression by Rosiglitazone on Atherosclerosis in Diabetes Patients with Cardiovascular History; NCT00116831) were presented by Richard W. Nesto, MD, Lahey Clinic, Burlington, MA, at the American Heart Association Scientific Sessions meeting in New Orleans.

Thiazolidinediones, such as rosiglitazone, have been shown to increase insulin sensitivity and reduce other cardiovascular (CV) risk factors but increase fluid retention and the risk of heart failure. It has been hypothesized that they also may reduce the progression of coronary atherosclerosis, although prior studies on CV outcomes have been mixed. The objective of the APPROACH trial was to assess the effect of the thiazolidinedione rosiglitazone versus the sulfonylurea glipizide on intravascular ultrasonography (IVUS) measures of atherosclerosis in native coronary arteries.

APPROACH was a multinational, double-blind, randomized, controlled trial that was conducted among subjects with type 2 diabetes and a clinical indication for angiography or percutaneous coronary intervention. Patients who had ≥1 nonintervened plaques with a 10% to 50% narrowing of the coronary artery were eligible for participation. The primary study endpoint was percent change in atheroma volume (PAV) from baseline to 18 months using IVUS, as analyzed by a blinded core laboratory. Secondary endpoints included changes in normalized total atheroma volume and atheroma volume of the most diseased 10-mm coronary artery segment.

Subjects were randomly assigned to receive rosiglitazone that was titrated to 8 mg/day (n=233) or glipizide that was titrated to 15 mg/day for 18 months (n=229). Metformin or insulin could be added after 3 months as needed to attain a target hemoglobin A1c (HbA1c) ≤7%. Other CV risk factors were managed according to regional guidelines and clinical judgment.

A total of 672 subjects enrolled in the study; 462 had both a baseline and 18-month IVUS. Study subjects had a mean age of 61 years (32% women), and a median of 4.8 years passed since their diabetes had been diagnosed. Eighteen percent of subjects were not on medication for their diabetes, 54% was on 1 medication, and 28% was on dual therapy. Patient characteristics were similar between both treatment groups except for blood pressure, which was higher in the glipizide group (131/76 vs 128/75 mm Hg), and creatinine, which was slightly higher in rosiglitazone subjects (1.02 vs 0.98 mg/dL; both p<0.05).

After 18 months, neither treatment produced a significant difference in the primary endpoint, PAV