

Lab Test Flags Those at Low Risk for Repeat VTE

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A simple and inexpensive laboratory test that measures thrombin generation can be used to identify venous thromboembolism patients at low risk of recurrence—those who are unlikely to benefit from indefinite anticoagulant treatments, reported Dr. Gregor Hron of the Medical University of Vienna, and his colleagues.

In the Austrian Study on Recurrent Venous Thromboembolism (AUREC), an ongoing prospective cohort study that enrolled 914 patients between 1992 and 2005, those patients without recurrent VTE were found to have significantly lower peak thrombin generation than patients with VTE recurrence, according to the researchers.

The mean patient age at first venous thromboembolism (VTE) was 47 years, and 55% of the patients were women.

Deep vein thrombosis was found in 55% of patients, and 46% had a pulmonary embolism. Patients with both conditions were classified as having pulmonary embolism.

The mean duration of oral anticoagulant therapy in the patients studied was 8 months, with a mean observation time after therapy was discontinued of 47 months.

According to Dr. Hron and colleagues, patients were enrolled after discontinua-

tion of vitamin K antagonist therapy. "For measurement of peak thrombin generation, blood was collected at a median of 13 months after discontinuation of anticoagulant therapy. Patients were seen at 3-month intervals and every 6 months thereafter," they said (JAMA 2006;296:397-402).

The researchers analyzed thrombin generation with an assay kit called Technothrombin TGA (Technoclone GmbH, Vienna) using a computer-controlled microplate reader and specially adapted software.

"Patients with a first spontaneous VTE and peak thrombin generation of less than 400 nm after discontinuation of vitamin K antagonists have a low risk of recurrence," said the researchers. Their likelihood of recurrence "was as low as 7% after 4 years," according to Dr. Hron and his colleagues.

When compared with those with higher levels, patients with peak thrombin generation less than 400 nm had a 60% lower risk of recurrence, and this group represented the majority of the total patient population.

When underlying coagulation factors were assessed, 242 (27%) patients were found heterozygous for the factor V Leiden mutation, and 18 (2%) were homozygous. The mean factor VIII level was 166 IU/dL and mean factor IX level was 119 IU/dL. The number of patients with the prothrombin G20210A mutation was 63 (7%).

Overall, VTE was seen to recur in 100 patients (11%)—69 men and 31 women—with deep vein thrombosis in 58 patients and pulmonary embolism in 42 patients. Those patients with recurrent VTE had higher concentrations of factor VIII levels (173 IU/dL vs. 165 IU/dL), and factor IX levels (127 IU/dL vs. 118 IU/dL). These patients also had a shorter observation period (32 months vs. 48 months) and were older (50 years vs. 47 years).

The factor V Leiden polymorphism was detected in 38% of patients with recurrence and in 27% of patients without recurrence. Nine patients with recurrence and 54 patients without recurrence showed the presence of factor II G20210A. Women and carriers of factor II G20210A had higher peak thrombin generation than men and patients without the mutation. There was no difference in peak thrombin generation in patients with or without factor V Leiden, or those patients with or without high factor VIII.

By the end of the study, a total of 194 of the original 914 patients were excluded for various medical reasons such as cancer, arterial disease or atrial fibrillation, or death, or were lost to follow-up.

"Using a simple and commercially available laboratory method developed to measure thrombin generation, we were able to identify patients in whom the long-term risk of recurrent VTE is almost negligible. Considering the incidence rates of severe or fatal hemorrhage related to anticoagulant therapy and the case-fatality rate of recurrent VTE, patients with low peak thrombin generation (less than 400 nm) would almost certainly not benefit from indefinite anticoagulant therapy," concluded the researchers. ■

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