VENOUS THROMBOEMBOLISM EXTENDED APIXABAN USE FOR VTE

Results of a double-blind, randomized, controlled trial, in which apixaban use was assessed in patients with venous thromboembolism (VTE) who had already completed 6–12 months of anticoagulation therapy, have been published in the *New England Journal of Medicine*. Uncertainty about whether anticoagulation therapy should be continued or ceased existed for all 2,486 patients enrolled in the AMPLIFY-EXT trial. The investigators found that a 12-month, twice-daily regimen of either 2.5 mg or 5.0 mg of apixaban was "effective, safe, and simple to use" in this patient population.

During the 1-year active study period, 11.6% of the placebo group reached the primary efficacy end point—symptomatic recurrent VTE (fatal or nonfatal pulmonary embolism or deep-vein thrombosis) or death from any cause—compared with 3.8% in the 2.5 mg apixaban group (relative risk [RR] 0.33, 95% CI 0.22-0.48) and 4.2% in the 5.0 mg apixaban group (RR 0.36, 95% CI 0.25-0.53). Over the same period, 8.8% of the placebo group experienced symptomatic recurrent VTE or death related to VTE, compared with 1.7% in both the 2.5 mg apixaban (RR 0.19, 95% CI 0.11-0.33) and 5.0 mg apixaban (RR 0.20, 95% CI 0.11-0.34) groups.

The primary safety end point, major bleeding, was not significantly different between the three treatment groups (0.5%, 0.2%, and 0.1% for placebo, 2.5 mg apixaban, and 5.0 mg apixaban, respectively). The rates of other adverse events were also similar between the three treatment groups.

The AMPLIFY-EXT investigators concluded, therefore, that "for patients with VTE for whom there is uncertainty about the benefits and risks of continued therapy, the results of this study provide a rationale for continuing anticoagulation therapy for an additional 12 months". They warn clinicians, however, that more data are needed for patients aged >75 years, for those with body weight <60 kg, and for individuals with moderate-to-severe renal impairment, because few such patients were included in the AMPLIFY-EXT trial. The investigators also highlight the need for additional studies to assess the extension of apixaban treatment beyond 18-24 months.

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