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RIVAROXABAN FOR THE TREATMENT OF SYMPTOMATIC VENOUS THROMBOEMBOLISM: IS THERE A NEED FOR INITIAL HEPARIN TREATMENT? A SUBGROUP ANALYSIS OF THE EINSTEIN DVT AND PE STUDIES

Poster Contributions
Hall C
Sunday, March 30, 2014, 9:45 a.m.-10:30 a.m.

Session Title: Vascular Medicine: Emerging Topics from a Rapidly Changing Landscape
Abstract Category: 33. Vascular Medicine: Venous Disease
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Background: In the EINSTEIN DVT and EINSTEIN PE studies, the majority of patients received heparins while venous thromboembolism (VTE) was confirmed and trial logistics were completed. In contrast to vitamin K antagonist (VKA) therapy, patients receiving rivaroxaban may not require initial heparin treatment.

Methods: To address whether or not receiving prestudy heparin influenced the rivaroxaban treatment effect compared with enoxaparin/VKA, we evaluated the 3-month incidence of recurrent VTE and the 2-week incidence of major and clinically relevant nonmajor bleeding in patients who received prestudy heparin versus those that did not in the EINSTEIN DVT and EINSTEIN PE studies.

Results: Of the 8,281 randomized patients, 6,937 (83.8%) received prestudy heparin and 1,344 (16.2%) did not. In patients who did not receive prestudy heparin, 3-month incidences of recurrent VTE were similar in the rivaroxaban (15/649 [2.3%]) and enoxaparin/VKA groups (13/695 [1.9%]) (adjusted hazard ratio [HR], 1.11; 95% confidence interval [CI], 0.52-2.37). In patients who received prestudy heparin, recurrent VTE occurred in 54/3,501 (1.5%) of rivaroxaban-treated patients and in 69/3,436 (2.0%) of enoxaparin/VKA-treated patients (adjusted HR, 0.74; 95% CI, 0.52-1.06. Pinteraction=0.32). The incidences of bleeding in the rivaroxaban and enoxaparin/VKA groups did not differ significantly among patients who received prestudy heparin compared with those who did not.

Conclusions: Although the majority of patients included in the EINSTEIN DVT and EINSTEIN PE studies used prestudy heparin, there were no notable differences found in the treatment effect of rivaroxaban versus enoxaparin/VKA in patients who did or did not receive prestudy heparin. Our findings confirm that an initial course of heparin is not required for patients with symptomatic VTE who are treated with rivaroxaban.