

Title: Pooled Data from Rivaroxaban Clinical Trials: Timing of Symptomatic VTE and Bleeding Events after THA

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Introduction: The typical hospital stay after total hip arthroplasty (THA) is as short as 4 days. However, the risk of venous thromboembolism (VTE) continues after this time. Pooled analysis of the RECORD1 and RECORD2 trials evaluated the efficacy, safety, and timing of events with rivaroxaban versus enoxaparin for VTE prevention after THA.

Methods: Patients (N=7,050) were randomized to receive oral rivaroxaban 10 mg once daily starting postoperatively (for 31–39 days) or subcutaneous enoxaparin 40 mg once daily starting preoperatively (for 31–39 days in RECORD1, and 10–14 days followed by placebo in RECORD2). The incidence and timing of symptomatic VTE and death during treatment and treatment-emergent bleeding (any, major, major including surgical site, major plus clinically relevant non-major [CRNM] after the first dose of study medication and up to 2 days after the last dose) were assessed.

Results: Rivaroxaban significantly reduced the incidence of symptomatic VTE and death versus enoxaparin regimens (0.44% vs 1.01%, respectively; $p=0.006$). Of these events, 73% and 86% occurred after day 4 with rivaroxaban and enoxaparin regimens, respectively. For the composite of major plus CRNM bleeding, 48% and 33% of events occurred after day 4 with rivaroxaban and enoxaparin regimens, respectively. There were no significant differences between groups for any treatment-emergent bleeding outcomes.

Conclusion: After THA, rivaroxaban significantly reduced symptomatic VTE and death compared with enoxaparin regimens with no significant difference in bleeding. Major plus CRNM bleeding was more likely to occur before day 4, whereas the majority of symptomatic venous thromboembolic events occurred after day 4.