

Title: A Pooled Analysis of Surgical Complications: Results from the RECORD Program

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Introduction: Surgical complications after total hip or total knee arthroplasty (THA or TKA) are a primary concern for surgeons and can increase the cost and length of hospitalization, re-admission rates, and incur additional surgeries. Such complications include a wide range of conditions including bleeding, infection, and hemarthrosis. The phase III RECORD program investigated the oral, direct Factor Xa inhibitor rivaroxaban for the prevention of venous thromboembolism after THA (RECORD1, 2) or TKA (RECORD3, 4). The focus of this analysis from the pooled data from the four RECORD studies was to investigate whether rivaroxaban regimens are similar to enoxaparin regimens in the incidence of surgical complications after THA and TKA.

Methods: Patients (N=12,729) were randomized to receive rivaroxaban 10 mg once daily for 35±4 days or enoxaparin 40 mg once daily for 35±4 days (RECORD1) or 12±2 days followed by placebo (RECORD2). In RECORD3 and 4 patients received prophylaxis for 12±2 days with rivaroxaban 10 mg once daily or enoxaparin 40 mg once daily (RECORD3) or enoxaparin 30 mg twice daily (RECORD4). Surgical safety outcomes were analyzed in the safety population over the total treatment duration pool.

Results: The incidence of serious adverse events related to surgery, such as post-procedural infection, operative hemorrhage, wound dehiscence, postoperative wound infection, incision site hemorrhage, and hemarthrosis, was similar in the rivaroxaban (30/6,183: 0.49%) and enoxaparin (35/6,200: 0.56%) groups.

Conclusion: These data suggest that surgical safety outcomes are unlikely to differ between rivaroxaban and enoxaparin regimens.