Rivaroxaban: An Oral, Direct Factor XA Inhibitor for the Prevention of Venous Thromboembolism in Total Knee Replacement Surgery – Results of the RECORD 3 Study

Lassen MR, Turpie AG, Rosencher N, Borris LC, Ageno W, Lieberman JR, Bandel TJ, Misselwitz F

ISTH 2007. Abstract O-S-006-B

INTRODUCTION

Rivaroxaban is a novel, oral, direct Factor Xa inhibitor. RECORD 3 is a phase III trial evaluating rivaroxaban 10 mg once daily in patients undergoing total knee replacement (TKR).

METHODS

This double-blind trial randomized 2531 patients undergoing TKR to rivaroxaban 10 mg or enoxaparin 40 mg once daily. Enoxaparin was started before surgery, and rivaroxaban 6–8 hours after surgery; both were continued for 10–14 days. The primary outcome was venous thromboembolism (VTE) diagnosed by mandatory venography, symptomatic VTE and all-cause mortality. The safety outcome was major bleeding.

RESULTS

1254 patients were randomized to rivaroxaban and 1277 to enoxaparin: 824 and 878, respectively, were evaluable for primary efficacy outcome; this occurred in 9.6% of the rivaroxaban group and 18.9% of the enoxaparin group (RRR 49%; $p<0.001$). Major VTE (the major secondary efficacy endpoint: proximal DVT + PE + VTE-related death) occurred in 1% and 2.6%, respectively (RRR 62%; $p=0.01$), and symptomatic VTE occurred in 1% and 2.7%, respectively. In the rivaroxaban and enoxaparin groups, major bleeding rates were 0.6% and 0.5%, and any bleeding 4.9% and 4.8%, respectively.

CONCLUSION

Rivaroxaban was significantly more effective than enoxaparin in the prevention of VTE after TKR in this study. Bleeding was similarly low in both groups. This study with rivaroxaban is the first demonstration of the effectiveness and safety of a fixed, unmonitored regimen of an oral Factor Xa inhibitor in antithrombotic therapy.

Abstract O-S-006-B presented at ISTH July 6-12, 2007, Geneva, Switzerland.