A Once-Daily, Oral, Direct Factor Xa Inhibitor, Rivaroxaban (BAY 59-7939), for Thromboprophylaxis After Total Hip Replacement

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Background—Rivaroxaban (BAY 59-7939)—an oral, direct Factor Xa inhibitor—could be an alternative to heparins and warfarin for the prevention and treatment of thromboembolic disorders.

Methods and Results—This randomized, double-blind, double-dummy, active-comparator–controlled, multinational, dose-ranging study assessed the efficacy and safety of once-daily rivaroxaban relative to enoxaparin for prevention of venous thromboembolism in patients undergoing elective total hip replacement. Patients (n=873) were randomized to once-daily oral rivaroxaban doses of 5, 10, 20, 30, or 40 mg (initiated 6 to 8 hours after surgery) or a once-daily subcutaneous enoxaparin dose of 40 mg (given the evening before and ≥6 hours after surgery). Study drugs were continued for an additional 5 to 9 days; mandatory bilateral venography was performed the following day. The primary end point (composite of any deep vein thrombosis, objectively confirmed pulmonary embolism, and all-cause mortality) was observed in 14.9%, 10.6%, 8.5%, 13.5%, 6.4%, and 25.2% of patients receiving 5, 10, 20, 30, and 40 mg rivaroxaban, and 40 mg enoxaparin, respectively (n=618, per-protocol population). No significant dose–response relationship was found for efficacy (P=0.0852). Major postoperative bleeding was observed in 2.3%, 0.7%, 4.3%, 4.9%, 5.1%, and 1.9% of patients receiving 5, 10, 20, 30, and 40 mg rivaroxaban, and 40 mg enoxaparin, respectively (n=845, safety population), representing a significant dose–response relationship (P=0.0391).

Conclusions—Rivaroxaban showed efficacy and safety similar to enoxaparin for thromboprophylaxis after total hip replacement, with the convenience of once-daily oral dosing and without the need for coagulation monitoring. When both efficacy and safety are considered, these results suggest that 10 mg rivaroxaban once daily should be investigated in phase III studies. **(*Circulation*. 2006;114:2374-2381.)**

Key Words: anticoagulants ■ coagulation ■ embolism ■ prevention ■ thrombosis

Currently, low-molecular-weight heparins (LMWHs) and vitamin K antagonists are used routinely for thromboprophylaxis after major orthopedic surgery.[1] Although they effectively reduce the incidence of deep vein thrombosis (DVT) and pulmonary embolism (PE),[1] a number of limitations restrict their use. Vitamin K antagonists, although orally administered, have a slow onset of action, interpatient variability, need for frequent monitoring, and potential drug interactions,[1] whereas LMWHs are administered parenterally.

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Rivaroxaban (BAY 59-7939) is an oral, direct Factor Xa (FXa) inhibitor. It has high oral bioavailability (relative bioavailability ≈80%),[2] a rapid onset of action, and predictable, dose-proportional pharmacokinetics and pharmacodynamics.[2,3] It has a half-life of 5 to 9 hours and is excreted rapidly, predominantly via renal elimination (66% of the total dose, with 36% of the dose excreted unchanged) and also by

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The online-only Data Supplement, which contains a list of the ODIXa-HIP Study Investigators, can be found at http://circ.ahajournals.org/cgi/content/full/CIRCULATIONAHA.106.642074/DC1.

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the biliary/fecal route.[3–6] Two phase II studies (n=1343) were performed to evaluate the efficacy and safety of a twice-daily regimen of rivaroxaban for 5 to 9 days, relative to the LMWH enoxaparin, for the prevention of venous thromboembolism (VTE) in patients undergoing major orthopedic surgery.[7,8] A wide (4-fold) dose range of rivaroxaban (total daily doses of 5 to 20 mg) compared favorably with enoxaparin.

Further evidence suggests that rivaroxaban may be suitable for once-daily administration. Phase I studies in healthy subjects showed that single doses of rivaroxaban have pharmacodynamic effects that persist for 24 hours.[2,9,10] Furthermore, via inhibition of Factor Xa activity, rivaroxaban ultimately diminishes thrombin generation. Rivaroxaban significantly inhibited peak and total amounts of thrombin generated and prolonged time to thrombin generation 24 hours after dosing in healthy subjects.[9]

Together, these studies led to the initiation of the Oral, Direct Factor Xa Inhibitor, BAY 59-7939, Given Once Daily in Patients Undergoing Total Hip Replacement (ODIXa-OD-HIP) study. This phase II study was performed to investigate the efficacy and safety of oral rivaroxaban administered once daily relative to that of subcutaneous enoxaparin in patients undergoing elective total hip replacement.

Methods

Study Design

The ODIXa-OD-HIP study was a randomized, double-blind, double-dummy, active-comparator–controlled, multinational, dose-ranging study to assess the efficacy and safety of oral rivaroxaban (Bayer HealthCare AG, Wuppertal, Germany) administered once daily relative to that of subcutaneous enoxaparin (Clexane/Lovenox, sanofi-aventis, Paris, France) for the prevention of VTE in patients undergoing elective, primary total hip replacement. The study was conducted in accordance with the Declaration of Helsinki. All study documentation was reviewed and approved by local independent ethics committees.

After written, informed consent was obtained, patients scheduled for elective, primary total hip replacement surgery were randomized to receive oral rivaroxaban or subcutaneous enoxaparin. Oral rivaroxaban (5, 10, 20, 30, or 40 mg) was administered 6 to 8 hours after surgery and once daily thereafter (every 24±2 hours) for an additional 5 to 9 days (within 2 hours of food). Enoxaparin 40 mg (0.4-mL prefilled syringes) was administered on the evening before surgery, at least 6 to 8 hours after wound closure in accordance with European practice, and then once daily every evening according to hospital routine for an additional 5 to 9 days. Patients received matching placebo tablets or injections, so that each patient received 2 tablets and an injection every evening. Mandatory bilateral venography was performed the day after the last dose of study drug. Patients attended a clinical follow-up visit 30 to 60 days later. Further thromboprophylaxis after venography was at the discretion of the investigator.

Patients

Men aged ≥18 years and postmenopausal women scheduled for elective, primary total hip replacement surgery were enrolled. Exclusion criteria included DVT, PE, myocardial infarction, transient ischemic attack, or ischemic stroke during the 6 months before the study. Also excluded were patients with intracerebral, intraocular, or gastrointestinal bleeding in the previous 6 months; patients taking drugs that might have affected the study outcome, such as other anticoagulants, platelet-aggregation inhibitors, or any other severe liver or renal impairment, medical conditions that may interfere with the study, or body weight <45 kg; and patients who abuse alcohol or drugs. Intermittent pneumatic compression was not permitted during the treatment period.

Outcome Measures

Efficacy

The primary efficacy end point—the composite of the incidence of any DVT (proximal and/or distal); nonfatal, symptomatic, objectively confirmed PE; and all-cause death—was evaluated 6 to 10 days after surgery, or earlier if the patient was symptomatic. Secondary efficacy end points included major VTE (defined as the composite of the incidence of proximal DVT; symptomatic, objectively confirmed PE; and VTE-related death) and symptomatic VTE.

Safety

The primary safety end point was the incidence of major bleeding, starting after the first postoperative dose of study drug but no later than 2 days after the last dose of study drug. Major bleeding was defined as follows[11]: fatal bleeding; bleeding into a critical organ (including retroperitoneal, intracranial, intraocular, or intraspinal bleeding); bleeding warranting treatment cessation; or clinically overt bleeding associated with a fall in hemoglobin ≥2 g/dL within 24 hours, leading to transfusion of at least 2 units of blood, or leading to reoperation. Other bleeding end points included clinically relevant, non–major bleeding events (defined as multiple-source bleeding; spontaneous hematoma >25 cm^2; excessive wound hematoma; macroscopic hematuria [spontaneous or lasting >24 hours if associated with an intervention]; spontaneous rectal bleeding; epistaxis, gingival bleeding, or bleeding after venipuncture for >5 minutes; hemoptysis; or hematemesis) and minor bleeding events (those that did not fulfill the criteria for major bleeding or clinically relevant, non–major bleeding events). Postoperative blood loss (via drain) and transfusion volumes were documented during the treatment period.

Other safety assessments included hematology and clinical chemistry laboratory tests, including liver function and coagulation tests.

Assessments

Patients were screened for DVT with standardized, mandatory, bilateral venography the day after their last dose of study drug (ie, 6 to 10 days after surgery), or sooner if signs and symptoms were present.[11] The venography method used was the Rabinov and Paulin technique,[12–14] with a standardized methodology in which a minimum of 9 films were used for each leg, each from a different projection. All venograms were assessed centrally by the Venography Adjudication Committee (Department of Radiology, Östra Hospital, Gothenburg, Sweden). Symptomatic PE was confirmed by pulmonary angiography, spiral computed tomography, or perfusion/ventilation lung scintigraphy plus chest radiography. In cases of death, an autopsy was performed if possible. All symptomatic VTEs and deaths occurring during the treatment or follow-up period were assessed centrally by the VTE Adjudication Committee (Central Clinic, Östra Hospital, Gothenburg, Sweden). All bleeding events were assessed centrally by the Bleeding Event Adjudication Committee. All adjudication committees were independent and blinded to treatment allocation.

An independent Data and Safety Monitoring Board continuously monitored efficacy and safety in this study. The Data and Safety Monitoring Board could unblind patients' study drug allocation and, in cases of insufficient efficacy or unacceptable safety, recommend amendment of the study protocol, which included discontinuation of the study or a treatment arm, according to prespecified criteria.

Sample Size Calculation

According to the initial study protocol, patients were randomized evenly (1:1:1:1:1) to receive 1 of 4 doses of rivaroxaban (10, 20, 30, or 40 mg once daily [OD]) or enoxaparin (40 mg OD). However, after the study was initiated, the results of 2 phase IIb studies

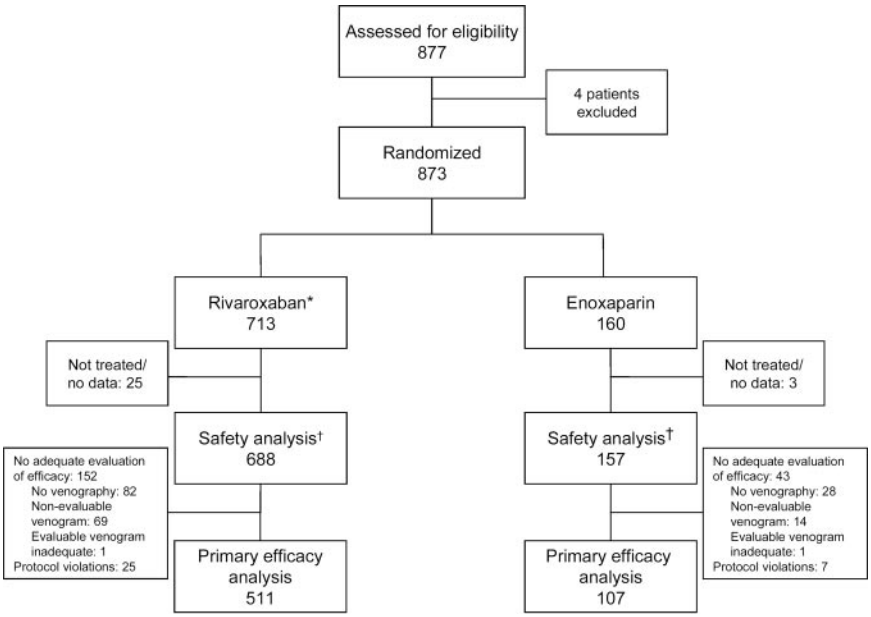

Figure 1. Flow of patients though the ODIXa-OD-HIP study. *Patients were randomized to receive 1 of 5 doses of rivaroxaban (5, 10, 20, 30, or 40 mg OD). †Patients eligible for the safety analysis had at least 1 dose of study drug and data allowing safety assessment.

anticipated in patients who had undergone major orthopedic surgery.[7,8] As a result, a 5-mg OD dose of rivaroxaban was included in the protocol after the study was initiated. On the basis of event rates of the primary efficacy end point of 10% to 25%, and assuming a linear trend in the dose–response relationship and a 23% invalidity rate, 135 subjects were required in each dose group to provide 90% power to detect a dose trend in the primary efficacy analysis. To achieve similar numbers of patients in each dose group despite the late start of the 5-mg OD dose group, patients were randomized 2:1:1:1:1:1 to 5, 10, 20, 30, and 40 mg rivaroxaban OD and 40 mg enoxaparin, respectively.

Statistical Analysis

Efficacy

The primary efficacy analysis—to determine a trend in the dose–response relationship between rivaroxaban and the primary efficacy end point—was performed in the per-protocol (PP) population with a logistic regression model, including the total daily dose of rivaroxaban and the country in which the patient was treated as explanatory variables. An identical supportive analysis was performed in the intention-to-treat (ITT) population.

A similar analysis, using logistic regression with the total daily dose of rivaroxaban as a covariate, was performed in the PP population to determine a trend in the dose–response relationship between rivaroxaban and major VTE (a secondary efficacy end point; because of the expected low incidence of major VTE, country effects were not considered in this analysis).

The PP population comprised patients who had received at least one dose of study medication and had data allowing assessment of safety (ie, the safety population), who had undergone surgery, had an adequate VTE assessment (adequate bilateral venography 6 to 10 days after surgery, or confirmed DVT, PE, or death up to 10 days after surgery) performed no later than 36 hours after the last dose of study drug, and who did not show any major protocol violations. All tests were 2 sided, with a type I error rate of $\alpha=5\%$.

Safety

The incidence of major bleeding was analyzed in the safety population with a logistic regression model, including the total daily dose of rivaroxaban as a covariate. In addition, each dose of rivaroxaban was compared with enoxaparin with the Fisher exact test. All

The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

Results

Study Population

Between November 2004 and July 2005, 877 patients were enrolled in this study, at 48 centers in 11 countries (Europe and Israel); 873 patients were randomized to receive rivaroxaban or enoxaparin (Figure 1; for further details, see the Data Supplement Figure). Twenty-one randomized patients did not receive study drug (18 in the rivaroxaban dose groups and 3 in the enoxaparin group). Of the remaining 852 patients, 695 received rivaroxaban (128, 142, 140, 143, and 142 patients received 5, 10, 20, 30, and 40 mg OD, respectively) and 157 received enoxaparin. The safety population comprised 845 patients (7 patients withdrew from the study before surgery). The primary analysis was performed in the PP population, which comprised 618 patients: 511 patients receiving rivaroxaban (94, 113, 106, 104, and 94 patients in the 5-, 10-, 20-, 30-, and 40-mg OD dose groups, respectively) and 107 patients receiving enoxaparin (Figure 1). A total of 29% of all randomized patients (255/873) were excluded from the primary efficacy analysis. The main reason for exclusion was inadequate evaluation of efficacy, which occurred in 195 patients, 110 of whom did not undergo bilateral venography, and venograms were considered inadequate for interpretation in 83 patients. In 2 patients, venography was performed before the prespecified time window, ie, before the fifth postoperative day. Other reasons for exclusion included protocol violations, such as violating the time interval between doses of study drug and taking prohibited medications.

All groups were well balanced with respect to age, sex, weight, body mass index, and the duration of surgery (Table

TABLE 1. Baseline Characteristics and Surgery Details for Study Patients (Safety Population; n=845)

Characteristics	Rivaroxaban 5 mg OD (n=128)	Rivaroxaban 10 mg OD (n=142)	Rivaroxaban 20 mg OD (n=139)	Rivaroxaban 30 mg OD (n=142)	Rivaroxaban 40 mg OD (n=137)	Enoxaparin 40 mg OD (n=157)
Age, mean (range), y	64.8 (28–84)	64.0 (27–87)	65.0 (27–93)	65.4 (31–86)	64.7 (27–83)	65.6 (30–89)
Female, n (%)	72 (56)	89 (63)	82 (59)	73 (51)	81 (59)	101 (64)
Weight, mean (range), kg	76.6 (45–118)	75.6 (45–111)	75.7 (47–120)	78.4 (49–130)	77.6 (50–126)	74.9 (45–116)
Body mass index, mean (range), kg/m^2	27.4 (17–46)	26.9 (18–49)	27.1 (18–41)	27.5 (20–43)	27.5 (19–40)	27 (16–39)
Surgery details						
Cemented hip prosthesis, n (%)	37 (28.9)	55 (38.7)	50 (36.0)	58 (40.8)	57 (41.6)	64 (40.8)
Duration of surgery, mean±SD, min	85±33	89±30	85±31	89±34	89±31	84±28
Type of anesthesia						
General, n (%)	64 (50)	49 (35)	42 (30)	56 (39)	42 (31)	60 (38)
Regional,* n (%)	62 (48)	93 (65)	96 (69)	84 (59)	95 (69)	97 (62)

*Spinal and epidural anesthesia.

surgery and first oral dose of rivaroxaban was 7 hours. The mean duration of treatment was 7 days for rivaroxaban and 8 days for enoxaparin—the difference is explained by the initiation of enoxaparin on the day before surgery and the initiation of rivaroxaban after surgery.

Efficacy Outcomes

The primary efficacy end point (composite of any DVT, PE, and all-cause death) was observed in 14.9%, 10.6%, 8.5%, 13.5%, and 6.4% of patients receiving 5, 10, 20, 30, and 40 mg rivaroxaban OD, respectively, compared with 25.2% of patients receiving enoxaparin (Table 2). Although there was a tendency toward a lower incidence of the primary efficacy end point with increasing doses of rivaroxaban (Table 2, Figure 2), statistical analysis did not detect a trend in this dose–response relationship (P=0.0852). Similar results were obtained in the ITT population (data not shown). No rivaroxaban dose arm was discontinued because of lack of efficacy.

No deaths were reported during the study (treatment and follow-up). Although there were no PEs reported in the PP population (Table 2), there was a PE in a patient in the ITT population who received 40 mg rivaroxaban OD, and one in a patient receiving 10 mg rivaroxaban OD who was only eligible for the safety analysis. There was one report of symptomatic DVT during the treatment period (1 distal DVT in the enoxaparin group [PP population]), and 3 during the follow-up period (2 proximal DVTs: 20 mg and 40 mg rivaroxaban; and 1 PE: 40 mg rivaroxaban).

The observed incidence of the secondary efficacy end point, major VTE (composite of proximal DVT, PE, and VTE-related death), was similar to enoxaparin in all rivaroxaban dose groups, except the 5-mg OD group, in which the incidence was 8.5%, compared with 2.8% for enoxaparin (Table 2). Statistical analysis demonstrated a significant trend in the dose–response relationship between rivaroxaban and major VTE (P=0.0072).

Safety Outcomes

The primary safety end point—major postoperative bleeding—was observed in 2.3%, 0.7%, 4.3%, 4.9%, and 5.1% of patients receiving 5, 10, 20, 30, and 40 mg rivaroxaban OD,

TABLE 2. Efficacy End Points and Their Composites (PP Population; n=618)

Parameter	Rivaroxaban 5 mg OD (n=94)	Rivaroxaban 10 mg OD (n=113)	Rivaroxaban 20 mg OD (n=106)	Rivaroxaban 30 mg OD (n=104)	Rivaroxaban 40 mg OD (n=94)	Enoxaparin 40 mg OD (n=107)
Primary efficacy end point,* n (%)	14 (14.9)	12 (10.6)	9 (8.5)	14 (13.5)	6 (6.4)	27 (25.2)
95% CI	8.4, 23.7	5.6, 17.8	4.0, 15.5	7.6, 21.6	2.4, 13.4	17.3, 34.6
DVT, n (%)	14 (14.9)	12 (10.6)	9 (8.5)	14 (13.5)	6 (6.4)	27 (25.2)
Proximal, n (%)	8 (8.5)	3 (2.7)	1 (0.9)	2 (1.9)	1 (1.1)	3 (2.8)
Distal only, n (%)	6 (6.4)	9 (8.0)	8 (7.5)	12 (11.5)	5 (5.3)	24 (22.4)
PE, n (%)	0	0	0	0	0	0
Death, n (%)	0	0	0	0	0	0
Major VTE,† n (%)	8 (8.5)	3 (2.7)	1 (0.9)	2 (1.9)	1 (1.1)	3 (2.8)
95% CI	3.7, 16.1	0.6, 7.6	0.0, 5.1	0.2, 6.8	0.0, 5.8	0.6, 8.0

*Components of primary efficacy end point: any DVT; nonfatal, symptomatic, objectively confirmed PE (no reports); and all-cause death (no reports).

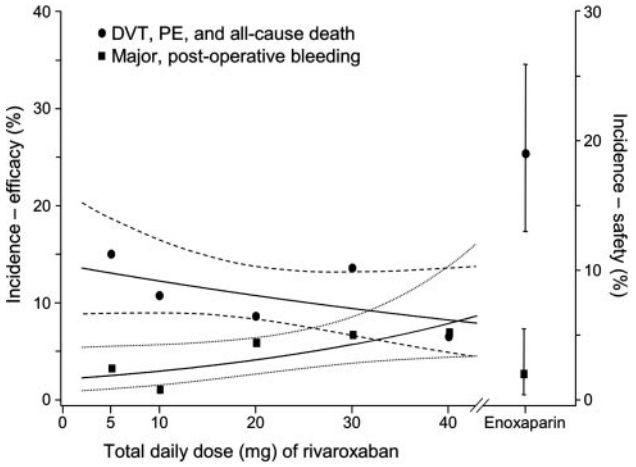

Figure 2. Dose–response relationships between rivaroxaban and the primary efficacy end point (DVT, non-fatal PE, all-cause death; PP population) and the primary safety end point (major postoperative bleeding events; safety population). The solid lines are the dose–response curves for rivaroxaban, estimated by logistic regression including total daily dose as a covariate. The dotted lines represent the 95% CIs for safety. The hatched lines represent the 95% CIs for efficacy.

respectively, compared with 1.9% of patients receiving enoxaparin (Table 3). There was a significant dose trend for major postoperative bleeding ($P=0.0391$; Figure 2). There were no significant differences in the incidences of major postoperative bleeding between any rivaroxaban dose and enoxaparin; however, this study was not powered to detect differences between individual rivaroxaban doses and enoxaparin.

No bleeding into a critical organ was reported, and all major postoperative bleeding events were confined to the surgical site. The majority of major bleeding events were due to clinically overt bleeding associated with a fall in hemoglobin ≥2 g/dL within 24 hours and/or leading to transfusion of at least 2 units of blood. The incidences of the secondary bleeding end points are also shown in Table 3. In general, proportions of patients requiring blood transfusions were similar across all rivaroxaban dose groups and for enoxaparin, and the volume of blood transfused was also similar (Table 4). No dose arm was stopped because of safety concerns.

Treatment-emergent increases (up to 7 days after the last dose of study drug) in alanine aminotransferase (ALT) or aspartate aminotransferase (AST) levels >3× the upper limit of normal (ULN) occurred in 3.0% to 5.4% and 3.4% to 6.2% of patients, respectively, in the rivaroxaban groups, compared with 7.1% of patients in the enoxaparin group (10/140 and 10/141 patients, respectively; Table 5). There did not seem to be dose dependency between rivaroxaban and increased liver enzymes.

One patient in the 30-mg rivaroxaban OD group had a combination of ALT >3× ULN and bilirubin >2× ULN 3 hours after receiving his first dose of study medication. Bilirubin returned to within normal limits the next day. ALT levels decreased despite continued study drug administration: They were <3× ULN on the last day of administration and within normal limits at the follow-up visit (34 days after receiving the last dose of study drug).

In addition, 1 patient in the 10-mg rivaroxaban OD group who had normal ALT and AST levels at baseline had raised ALT and AST 3 days after surgery (approximately 2× ULN; bilirubin was within normal limits). The patient received study medication for 7 days after surgery, according to the protocol. Liver enzymes continued to rise during the follow-up period, with ALT and AST >3× ULN 59 days after receiving the last dose of study drug, and 14 days later. An ultrasound examination 99 days after surgery revealed cholecystolithiasis.

Discussion

The ODIXa-OD-HIP study demonstrated that oral rivaroxaban given once daily postoperatively was equally efficacious

TABLE 3. Bleeding End Points (Safety Population; n=845)

	Rivaroxaban					Enoxaparin
Bleeding Classification	5 mg OD (n=128)	10 mg OD (n=142)	20 mg OD (n=139)	30 mg OD (n=142)	40 mg OD (n=137)	40 mg OD (n=157)
Major postoperative bleeding*, n (%)	3 (2.3)	1 (0.7)	6 (4.3)	7 (4.9)	7 (5.1)	3 (1.9)
95% CI	0.5, 6.7	0.0, 3.9	1.6, 9.2	2.0, 9.9	2.1, 10.2	0.4, 5.5
Components of major bleeding†						
Fatal/critical bleeding, n (%)	0	0	0	0	0	0
Bleeding leading to reoperation, n (%)	0	0	1 (0.7)	1 (0.7)	0	0
Clinically overt bleeding leading to treatment cessation, n (%)	0	0	1 (0.7)	0	1 (0.7)	0
Clinically overt bleeding with a fall in hemoglobin, n (%)	2 (1.6)	0	4 (2.9)	6 (4.2)	5 (3.6)	1 (0.6)
Clinically overt bleeding leading to blood transfusion, n (%)	3 (2.3)	1 (0.7)	5 (3.6)	6 (4.2)	6 (4.4)	3 (1.9)
Clinically relevant non–major bleeding, n (%)	2 (1.6)	3 (2.1)	1 (0.7)	3 (2.1)	4 (2.9)	5 (3.2)
Minor bleeding, n (%)	5 (3.9)	5 (3.5)	6 (4.3)	8 (5.6)	14 (10.2)	6 (3.8)

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