



Rivaroxaban Reduces Hospitalizations for Thromboembolic Events in Patients With Peripheral Artery Disease After Revascularization in Those With and Without Chronic Kidney Disease

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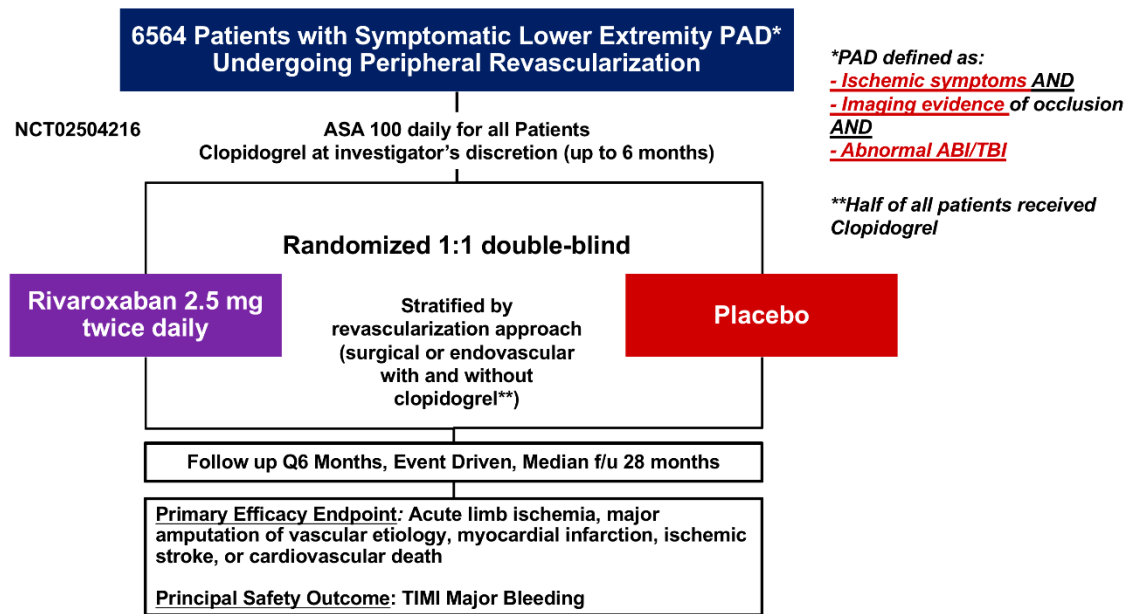
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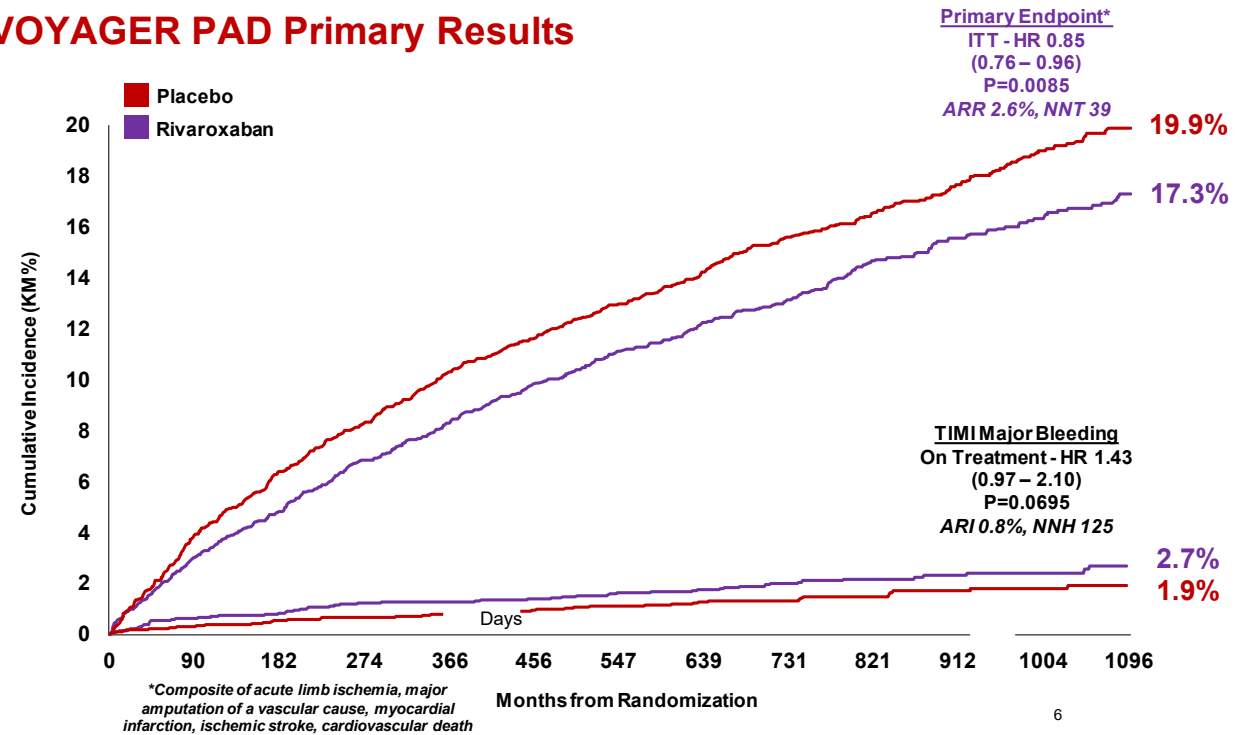
Background

- PAD affects > 200 million individuals worldwide. CKD confers a higher prevalence of PAD at 24% to 32% compared with 9% for those without renal impairment

VOYAGER PAD TRIAL DESIGN



VOYAGER PAD Primary Results



Objectives

- To evaluate whether, in the VOYAGER PAD* trial, the effects of rivaroxaban on rehospitalization and bleeding in patients with CKD** were consistent with the overall cohort:
 - **Key Efficacy Outcome:** hospitalization for a coronary or peripheral event of a thrombotic nature***
 - **Principal Safety Outcome:** TIMI major bleeding

**VOYAGER PAD*

- *6564 patients randomized to rivaroxaban 2.5mg twice daily*

***CKD*

- *Defined as eGFR < 60*
- *Individuals with eGFR < 15, on HD, or requiring RRT were excluded from this trial*

****Key Efficacy Outcome*

- *Prespecified secondary outcome*
- *Positive outcome in VOYAGER trial, $p < 0.001$*
- *Kaplan–Meier estimates for cumulative incidence of each prespecified outcome were assessed at ~3-years*

Baseline Characteristics by CKD Category

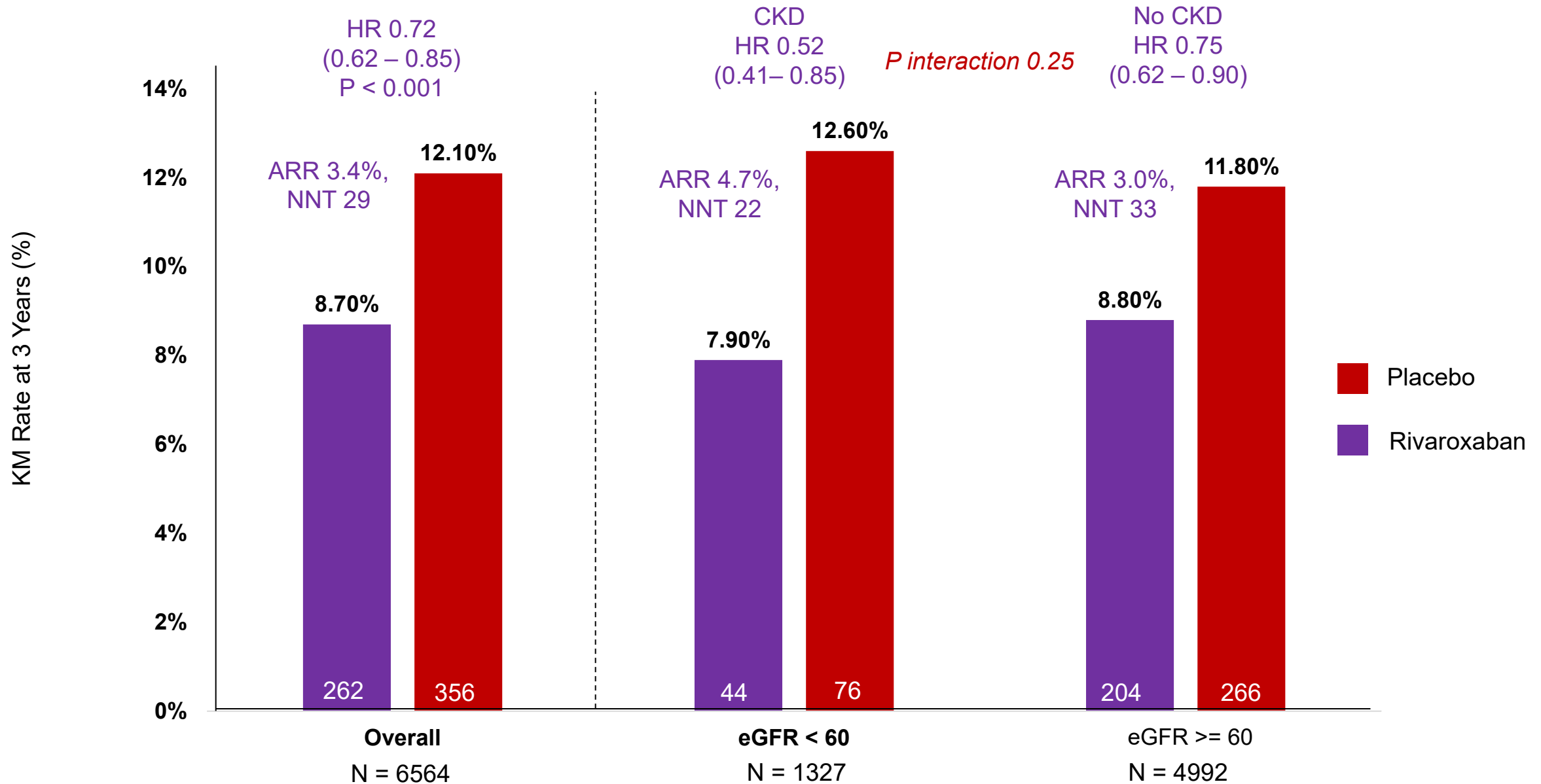
	CKD		No CKD	
	Rivaroxaban	Placebo	Rivaroxaban	Placebo
n	661	666	2499	2493
Age, years	73 (8)	72 (8)	66 (8)	66 (8)
Female, %	37	39	23	23
Race, %				
White	71	74	82	83
Asian	25	20	13	14
Black / African American	2	3	2	2
Hypertension, %	92	91	79	79
Diabetes Mellitus, %	51	54	37	36
Current Smoker, %	22	21	38	38
Body Mass Index, kg/m²	27 (5)	27 (5)	26 (5)	26 (5)
Index ABI at Screening (median)	0.57	0.57	0.55	0.55
Prior Limb Revascularization (yes),	37	38	35	34
Endovascular Approach, %	76	74	64	64
eGFR, ml/min/1.73m²	48 (9)	48 (9)	87 (23)	86 (19)

Chronic kidney disease (CKD) defined as eGFR < 60ml/min/1.73m² via the Modification of Diet in Renal Disease Study equation. Values are mean (standard deviation) or percentage

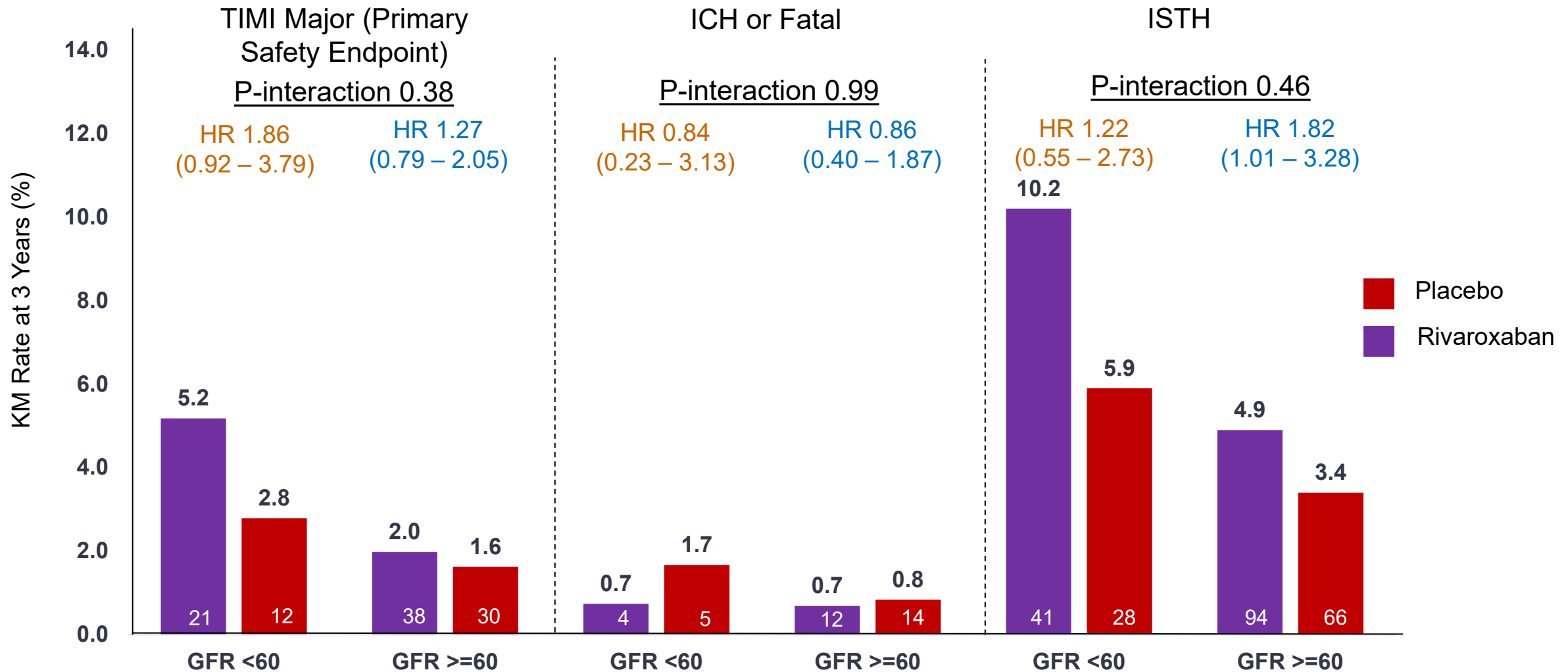
96.8% with CKD Stage 3 (eGFR 30–59), 3.1% with CKD Stage 4 (eGFR 15–29), 0.1% with CKD Stage 5 (eGFR < 15)

All p values > 0.05

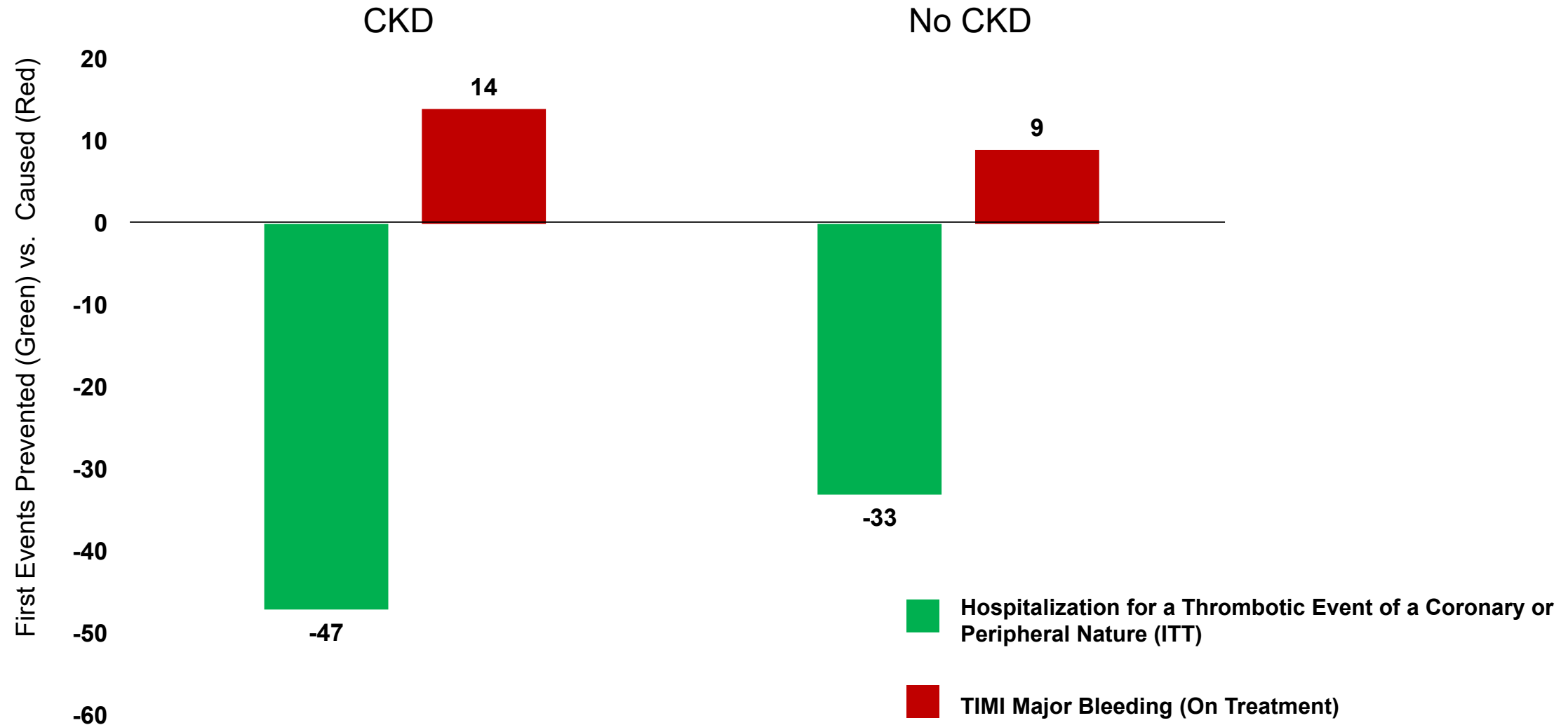
Rivaroxaban Reduced Hospitalizations for Coronary or Peripheral Events of a Thrombotic Nature in Patients With or Without CKD



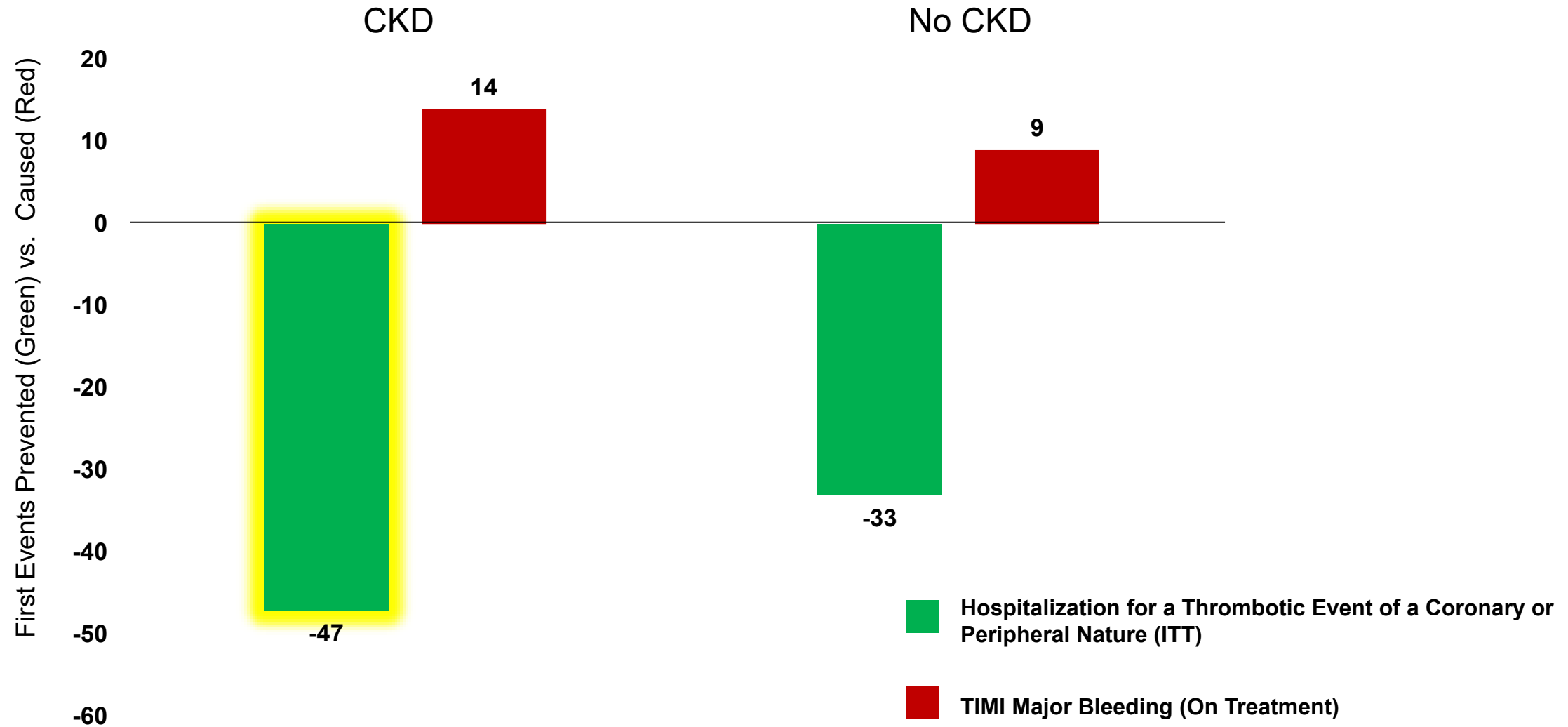
TIMI Major and ISTH Bleeding Were More Frequent With Rivaroxaban in Patients With or Without CKD



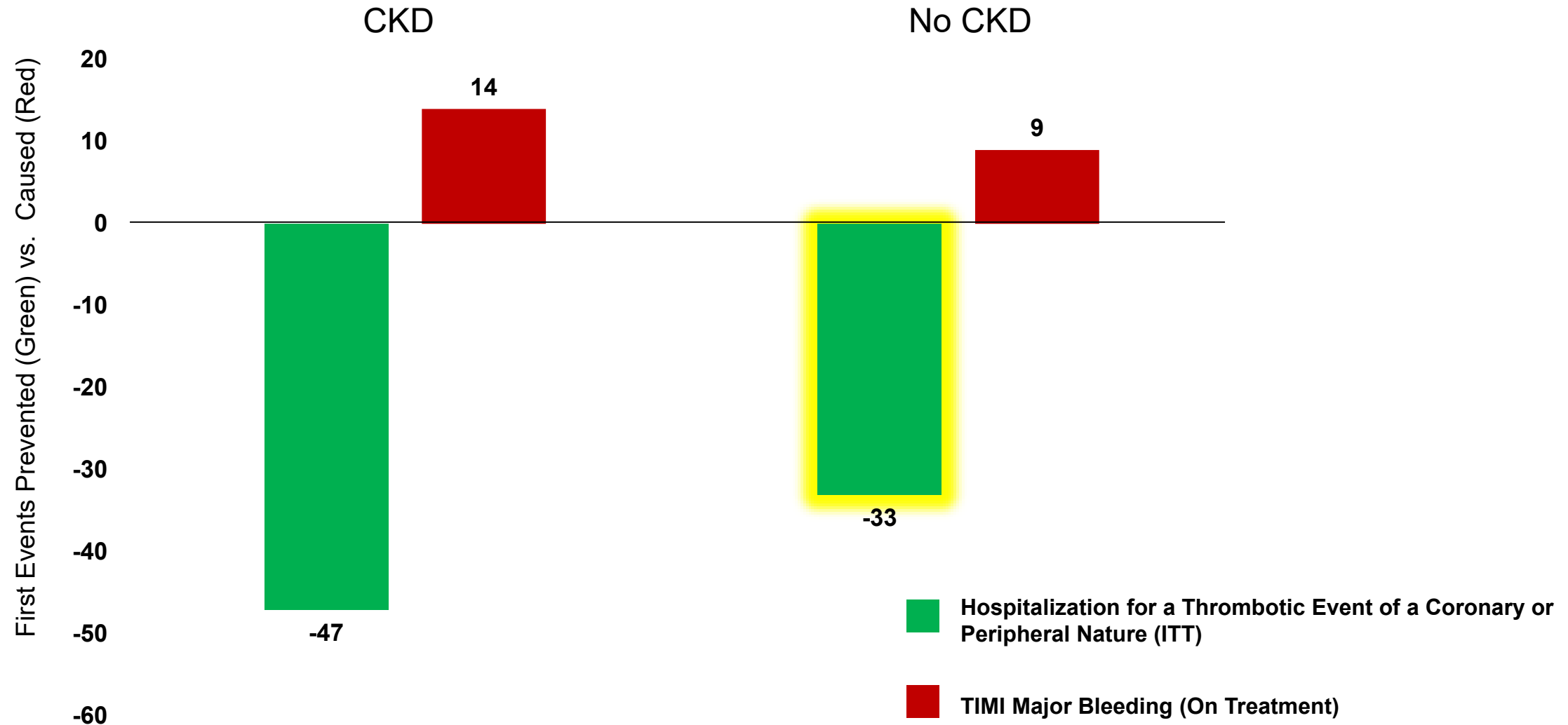
Events Prevented Versus Caused for 1000 Patients With and Without CKD Over 3 Years



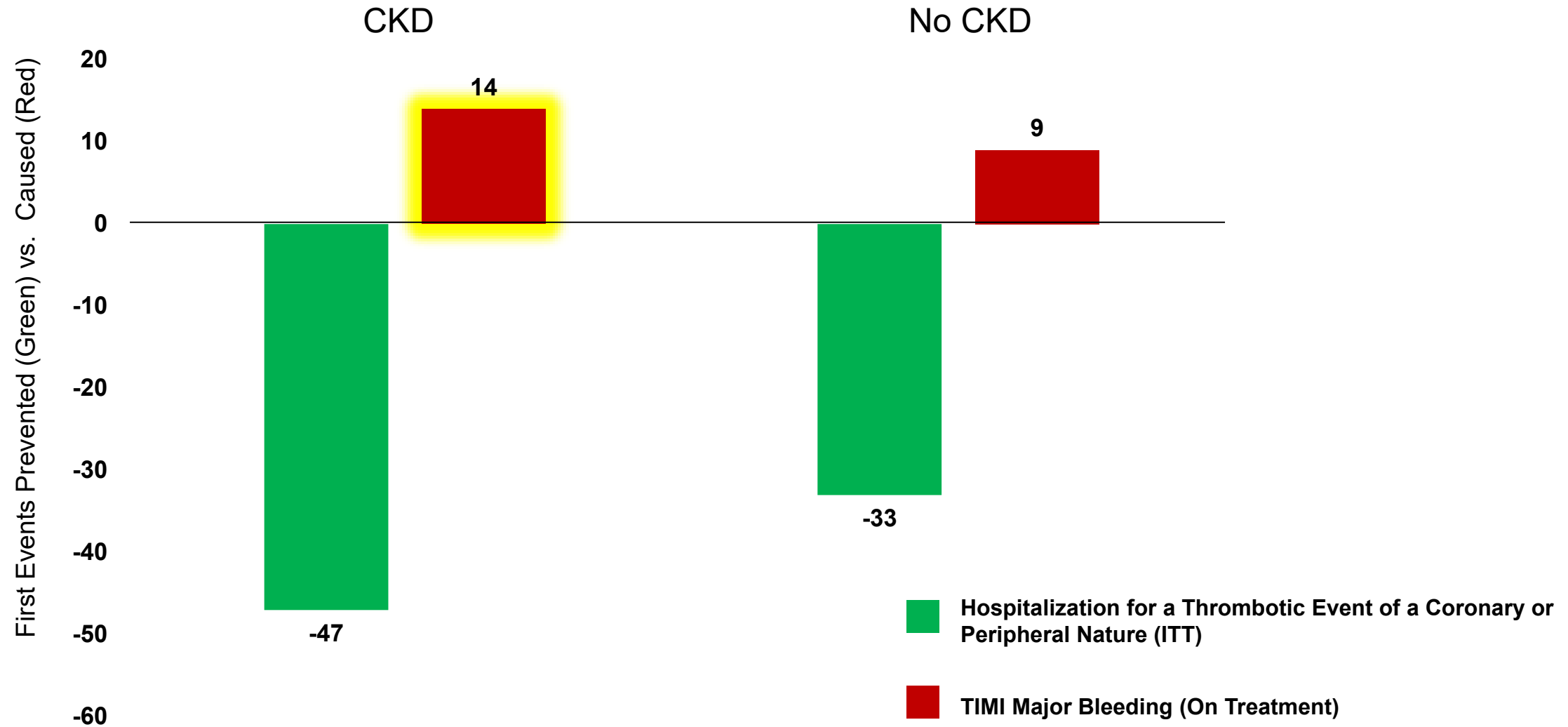
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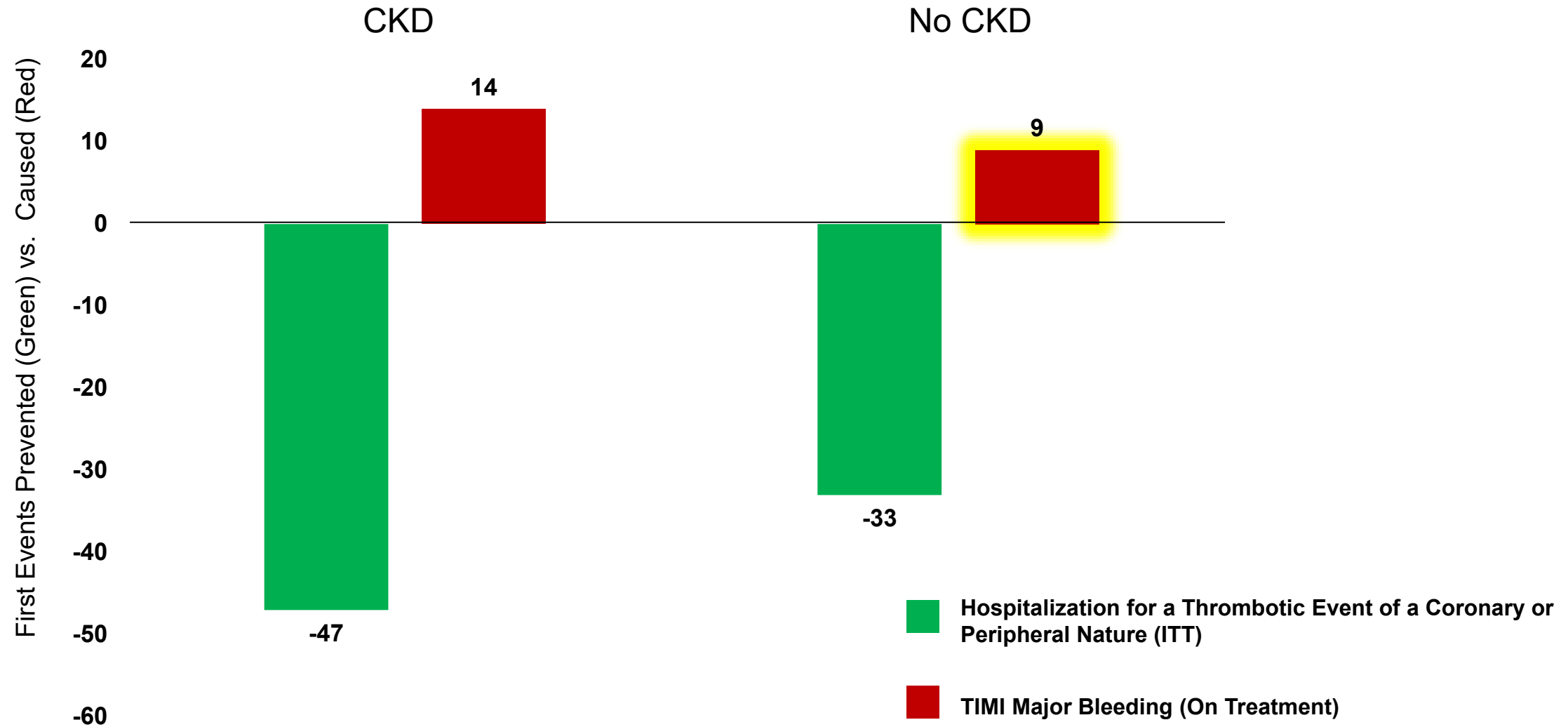
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Events Prevented Versus Caused for 1000 Patients With and Without CKD Over 3 Years



Events Prevented Versus Caused for 1000 Patients With and Without CKD Over 3 Years



Summary & Conclusions

- PAD patients with CKD are at heightened risk for perioperative, periprocedural, and long-term complications following LER
- A strategy of rivaroxaban 2.5 mg twice daily plus aspirin vs. aspirin alone reduces hospitalizations for coronary or peripheral events of a thrombotic nature in patients with recent LER with or without CKD
- There is a higher absolute benefit with this strategy among those with CKD compared to those without CKD
- Although patients with CKD are at higher bleeding risk overall, the bleeding risk with rivaroxaban was similar in patients with or without CKD
- Rivaroxaban demonstrated net clinical benefit for reducing hospitalizations in patients with or without CKD