An OPen-label, Randomized, Controlled, Multicenter Study ExplorIng TwO TreatmeNt StratEgiEs of Rivaroxaban and a Dose-Adjusted Oral Vitamin K Antagonist Treatment Strategy in Subjects With Atrial Fibrillation Who Undergo Percutaneous Coronary Intervention PIONEER AF-PCI

Purpose: To compare the safety and bleeding rates of 2 rivaroxaban treatments (either a thienopyridine or DAPT) or standard care using triple therapy with a vitamin K antagonist (VKA) in AF patients with PCI.

Trial Design: Open-label, randomized, controlled, multicenter trial; 2,124 patients with atrial fibrillation who had PCI were randomized 1:1:1 to either 1) rivaroxaban 15 mg qd + clopidogrel 75 mg daily for 12 months, 2) rivaroxaban 2.5 mg bid (with DAPT of 1, 6, or 12 months) , or 3) standard treatment - dose-adjusted VKA qd (with DAPT of 1, 6, or 12 months). 12-month f/u.

Primary Safety Endpoint: % of clinically significant bleeding over 12 months (composite of major and minor bleeding).

Trial Results	Group 1	Group 2	Group 3 – Std. Tx.
Clinically significant bleeding	16.8%	18.0%	26.7%
CV Death	6.5%	5.6%	6.0%

Conclusions: Atrial fibrillation patients having PCI with stents had lower rates of significant bleeding with either of two low doses of rivaroxaban compared to the current standard triple therapy.

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