2020

RIVER TRIAL

Rivaroxaban in Patients with Atrial Fibrillation and a Bioprosthetic Mitral Valve

AMERICAN COLLEGE of CARDIOLOGY

Randomized, noninferiority, open-label controlled trial

Objective: To assess the safety and efficacy of rivaroxaban compared with warfarin for patients with a bioprosthetic mitral valve and evidence of atrial fibrillation (AF) or flutter (AFL).

1005 patients

Inclusion criteria: Patients ≥18 years of age with AF or AFL, bioprosthetic mitral valve, receiving or planned use of oral anticoagulant for thromboembolism prophylaxis >48 hours from mitral valve surgery.

Rivaroxaban (N=500)		Warfarin (N=505)
	PRIMARY OUTCOME	
347.5	Mean time to death, major adverse cardiac events, major bleeding (days) P<0.001 for noninferiority	340.1
	SECONDARY OUTCOME	
3.4	Cardiovascular death or thromboembolic event % HR 0.65; 95% CI 0.35–1.20	5.1
0.6	Any stroke % HR 0.25; 95% CI 0.07-0.88	2.4

Conclusion: In patients with atrial fibrillation and a bioprosthetic mitral valve, rivaroxaban was noninferior to warfarin with respect to the mean time until the primary outcome of death, major cardiovascular events, or major bleeding at 12 months.

Guimarães HP, Lopes RD, de Barros e Silva PGM, et al. Rivaroxaban in Patients with Atrial Fibrillation and a Bioprosthetic Mitral Valve. *N Engl J Med* 2020; Nov 14:[Epub ahead of print].