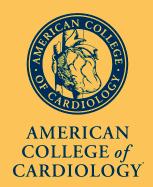
RIVER TRIAL



Rivaroxaban in Patients with Atrial Fibrillation and a Bioprosthetic Mitral Valve

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.