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INVICTUS

Rivaroxaban in Rheumatic Heart Disease-
Associated Atrial Fibrillation

International, Open-Label, Randomized Clinical Trial

OBJECTIVE: To investigate the efficacy of rivaroxaban vs. vitamin K antagonist among patients with atrial fibrillation (AFib) and rheumatic heart disease.

4,531
PATIENTS

INCLUSION CRITERIA: Patients with AFib and rheumatic heart disease with $CHA_2DS_2-VASc \geq 2$, a mitral-valve area of no more than 2 cm², left atrial spontaneous echo contrast, or left atrial thrombus.



RIVAROXABAN
(N=2,275)

vs.



VITAMIN K ANTAGONIST
(N=2,256)

PRIMARY ENDPOINT

Composite of stroke, systemic embolism, myocardial infarction, or death from vascular or unknown cause, for rivaroxaban vs. vitamin K antagonist: 8.21%/year vs. 6.49%/year, $p < 0.001$

SECONDARY ENDPOINT

Stroke: 1.32%/year vs. 0.94%/year
All-cause death: 7.95%/year vs. 6.35%/year
Major bleeding: 0.67%/year vs. 0.83%/year, $p = 0.18$

CONCLUSION

Among patients with AFib with rheumatic heart disease, treatment with vitamin K antagonist therapy led to a lower rate of a composite of stroke, systemic embolism, myocardial infarction, or death from vascular or unknown causes vs. rivaroxaban, without significant differences in bleeding.

Connolly SJ, Karthikeyan G, Ntsekhe M, et al. Rivaroxaban in Rheumatic Heart Disease–Associated Atrial Fibrillation. *N Engl J Med* 2022; Aug. 28: [Epub Ahead of Print].

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