Real-world effectiveness and the safety of anticoagulant treatment in elderly non-valvular atrial fibrillation in the ANAFIE registry, the largest real-world elderly AF registry

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On behalf of ANAFIE registry

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Background: The optimal anticoagulant regimen for elderly AF has not been well elucidated, because this population, especially the very elderly (≥85 years), have not been sufficiently represented in most randomized controlled clinical trials for stroke prevention in non-valvular AF (NVAF).

Purpose: The ANAFIE registry was designed to evaluate the real-world anticoagulant treatment status of elderly (≥75 years) NVAF patients including >8,000 very elderly patients. In this main analysis of the ANAFIE, the incidence of stroke or systemic embolic events (stroke/SEE), and major bleeding were compared between warfarin (WF) and direct oral anticoagulants (DOACs).

Methods: A total of 33,018 NVAF patients aged ≥75 years was enrolled in the ANAFIE, and followed for 2 years. The incidence of stroke/SEE and major bleeding by type of anticoagulants (WF and all DOACs) was estimated using Kaplan-Meier method. Hazard ratio (HR) and 95% confidence interval (95% CI) were calculated by Cox proportional hazard model.

Results: In the analysis set of 32,099 patients, the mean age was 81.5 years. 23,738 (74%) were <85 years and 8,361 (26.0%) were ≥85 years. 92.5% of the whole population used anticoagulants including WF (27.6%) or DOACs (72.3%). The ratio of each DOAC was dabigatran 7.8%, rivaroxaban 21.5%, apixaban 26.9% and edoxaban 16.1%. Stroke/SEE and major bleeding was observed in 396 patients (1.24/100 patient-years [py]) and 279 patients (0.87/100py). The time in therapeutic range for patients <85 years and ≥85 years in the WF group was 76.7% and 72.2%, respectively. The incidence of stroke/SEE was numerically lower in patients taking any DOAC vs. WF regardless of age group (<85 years [HR 0.83] and ≥85 years [HR 0.71]). Major bleeding was also lower vs. WF in both age groups (<85 years [HR 0.60] and ≥85 years [HR 0.65]).

Conclusion: In elderly NVAF patients enrolled in the ANAFIE registry, the incidence of stroke/SEE and major bleeding was lower in patients taking a DOAC compared with WF for all patients ≥75 years, even for very elderly patients.

		WF		DOACs		HR (95% CI) vs WF
		Event n / n	Event rate (/100 py)	Event n / n	Event Rate (/100 py)	
Stroke/SEE	Total	118 / 7,975	1.45	239 / 20,960	1.12	0.77 (0.62, 0.96)
	<85 years	72 / 5,683	1.25	168 / 15,950	1.04	0.83 (0.63, 1.10)
	≥85 years	46 / 2,292	1.96	71 / 5,010	1.39	0.71 (0.49, 1.03)
Major Bleeding (ISTH)	Total	100 / 7,993	1.23	159 / 21,036	0.75	0.61 (0.47, 0.78)
	<85 years	67 / 5,685	1.16	112 / 16,005	0.69	0.60 (0.44, 0.81)
	≥85 years	33 / 2,308	1.41	47 / 5,031	0.92	0.65 (0.42, 1.02)