

# The atrial Fibrillation Real-World (RW) Management Registry in the Middle East & Africa (The FLOW-AF registry): Patient Characteristics, Treatment Patterns and Outcomes

Hersi, Ahmad<sup>1</sup>; Almahmeed, Wael A.<sup>2</sup>; Khoury, Maurice<sup>3</sup>; Khalife, Natasha<sup>4</sup>; Gamaleldin, Mohamed Fathy Soliman<sup>5</sup>; Kherraf, Sid Ahmed<sup>5</sup>; Lopes, Renato D.<sup>6</sup>; Sobhy, Mohamed A.<sup>7,8,9</sup>

<sup>1</sup>King Saud University, Faculty of Medicine, Riyadh, Kingdom of Saudi Arabia; <sup>2</sup>Cleveland Clinic Abu Dhabi, Abu Dhabi, UAE; <sup>3</sup>American University of Beirut, Cardiology Department, Beirut, Lebanon; <sup>4</sup>IQVIA, Real-World Evidence, Dubai, UAE; <sup>5</sup>Pfizer Gulf, Dubai, UAE; <sup>6</sup>The Duke Clinical Research Institute, Duke University School of Medicine, Durham, North Carolina, USA; <sup>7</sup>Alexandria University, Alexandria, Egypt; <sup>8</sup>International Cardiac Center (ICC) Hospital, Alexandria, Egypt; <sup>9</sup>Cardiovascular Research, Education & Prevention Foundation (CVREP) Foundation, Egypt

## BACKGROUND

- Atrial Fibrillation (AF) is characterized by uncoordinated atrial activation with subsequent loss of atrial mechanical function.<sup>1</sup> It is a major risk factor for stroke, transient ischemic attack (TIA), myocardial infarction (MI), and heart failure (HF).<sup>2,3</sup>
- Nonvalvular atrial fibrillation (NVAF) is defined as AF that occurs in the absence of both mechanical prosthetic heart valves and moderate-to-severe mitral stenosis (usually of rheumatic origin); NVAF contributes to 77.0% to 91.0% of AF cases.<sup>4,5</sup>
- Limited real-world (RW) data on NVAF are available from the Middle east (ME) and Africa. It is well recognized that the characteristics of NVAF patients in this region may be different from the West in terms of a younger population and high prevalence of obesity, diabetes, and smoking.<sup>6</sup>
- The aim of the FLOW-AF registry was to evaluate the characteristics, treatment patterns, and clinical outcomes of patients newly diagnosed with NVAF in Egypt, Lebanon, the Kingdom of Saudi Arabia (KSA), and United Arab Emirates (UAE).

## METHODS

- A multi-center, prospective observational study that enrolled newly diagnosed NVAF patients from 26 sites across Egypt, Lebanon, KSA, and UAE, over 12 months.
- Patient inclusion criteria: Male/female aged ≥18 years, newly diagnosed with NVAF (within enrolment period or ≤90 days before baseline visit) for whom care had been initiated by the treating physician for stroke/systemic embolism (SE) prevention.
- Patient exclusion criteria: Severe psychiatric/other disease or circumstance that compromised study participation; participation in an interventional clinical trial at baseline; AF with a generally reversible cause; mechanical heart valves/valve disease expected to require valve replacement; medical conditions other than AF requiring chronic use of vitamin K antagonists (VKA)/non-VKA oral anticoagulant (NOAC); pregnant/breast-feeding women.
- Data were collected at enrollment (baseline), 6-months, and 12-months follow-up. Baseline data included demographics, AF characteristics, medical history, risk factors, vital signs/lab assessments, and anti-thrombotic treatment patterns. Follow-up data included clinical outcomes, treatment patterns, lab assessments, vital signs, and adverse events.
- The registry was conducted in accordance with local regulatory requirements and Guidelines for Good Pharmacoepidemiological Practices (GPP).

## RESULTS

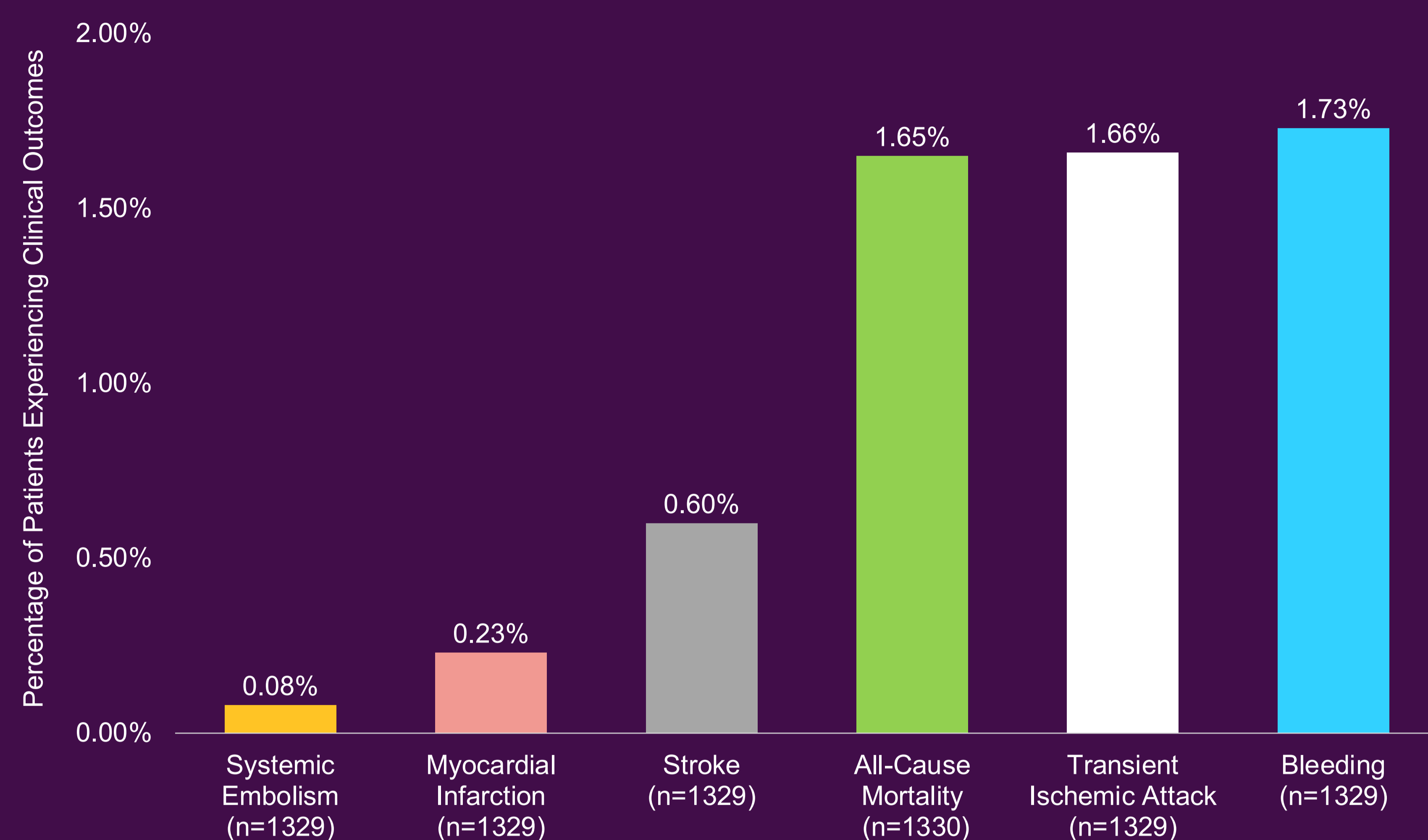
- A total of 1549 patients were screened, of which 1418 (91.54%) were enrolled (Egypt: n=723, 50.99%; Lebanon: n=321, 22.64%; UAE: n=198, 13.96%; and KSA: n=176, 12.41%) (Table 1).
- Overall, 747 patients (52.68%) were male, mean (standard deviation [SD]) age was 64.50 (14.18) years, and almost half were obese (n=654, 46.98%). The overall mean (SD) time since NVAF diagnosis was 19.29 (24.24) days (Table 1).
- Common comorbidities included hypertension (n=881, 62.17%), hypercholesterolemia (n=505, 35.64%), diabetes mellitus (DM) (n=474, 33.43%), coronary artery disease (CAD) (n=304, 21.44%), and congestive heart failure (CHF)/left ventricular dysfunction (n=262, 18.48%) (Table 1).
- The mean (SD) CHA<sub>2</sub>DS<sub>2</sub>-VASc (CHF/left ventricular systolic function, hypertension, age >75 years [doubled], type 2 DM, previous stroke, TIA or thromboembolism [doubled], vascular disease, age 65-75 years, and sex), and HAS-BLED (hypertension, abnormal renal/liver function, stroke, bleeding history/predisposition, labile International Normalised Ratio (INR), age ≥65, drugs/alcohol history/medications predisposing to bleeding) risk scores were 2.65 (1.62) and 1.58 (1.15), respectively (Table 1).
- Overall, a total of 1581 antithrombotic treatments were received at baseline; NOACs were most commonly used (n=1041, 65.84%), followed by VKAs (n=204, 12.90%), anti-platelet therapy (n=259, 16.38%), and other anti-thrombotic therapy (n=67, 4.24%) (Figure 1).

## CONCLUSION

- The FLOW-AF study provides valuable insights into newly diagnosed NVAF patients' characteristics, treatment patterns, and one-year outcomes in the RW ME setting.
- Rates of clinical outcomes, including stroke, SE, bleeding, cardiovascular mortality, and all-cause mortality were low.
- The ME patient population was younger, and had lower mean baseline CHA<sub>2</sub>DS<sub>2</sub>-VASc and HAS-BLED scores compared with Europe and other regions.
- Longer patient follow-up is required to comprehensively assess clinical outcomes in this ME patient population, and support data comparisons across different regions.

Overall, over one year, **5.9% of patients experienced at least one of the assessed clinical outcomes**, and each clinical outcome occurred at a rate ranging between 0.08%-1.73% (Figure 2).

Figure 2: Clinical outcomes during follow up



The rates of clinical outcomes over one year in FLOW-AF ME study were low compared with studies conducted in Europe and other regions<sup>7</sup>.

*This may be attributed to a younger patient population with relatively low baseline stroke and bleeding risk scores, and higher use of OAC, particularly NOAC, which are recommended as the preferred AF treatment option due to favorable safety profile and association with lower mortality rates.*

**ACC.23**  
TOGETHER WITH  
**WCC**

Bristol Myers Squibb/Pfizer Alliance has obtained the appropriate permissions to externally share this material with Healthcare Professionals upon request

TABLE 1

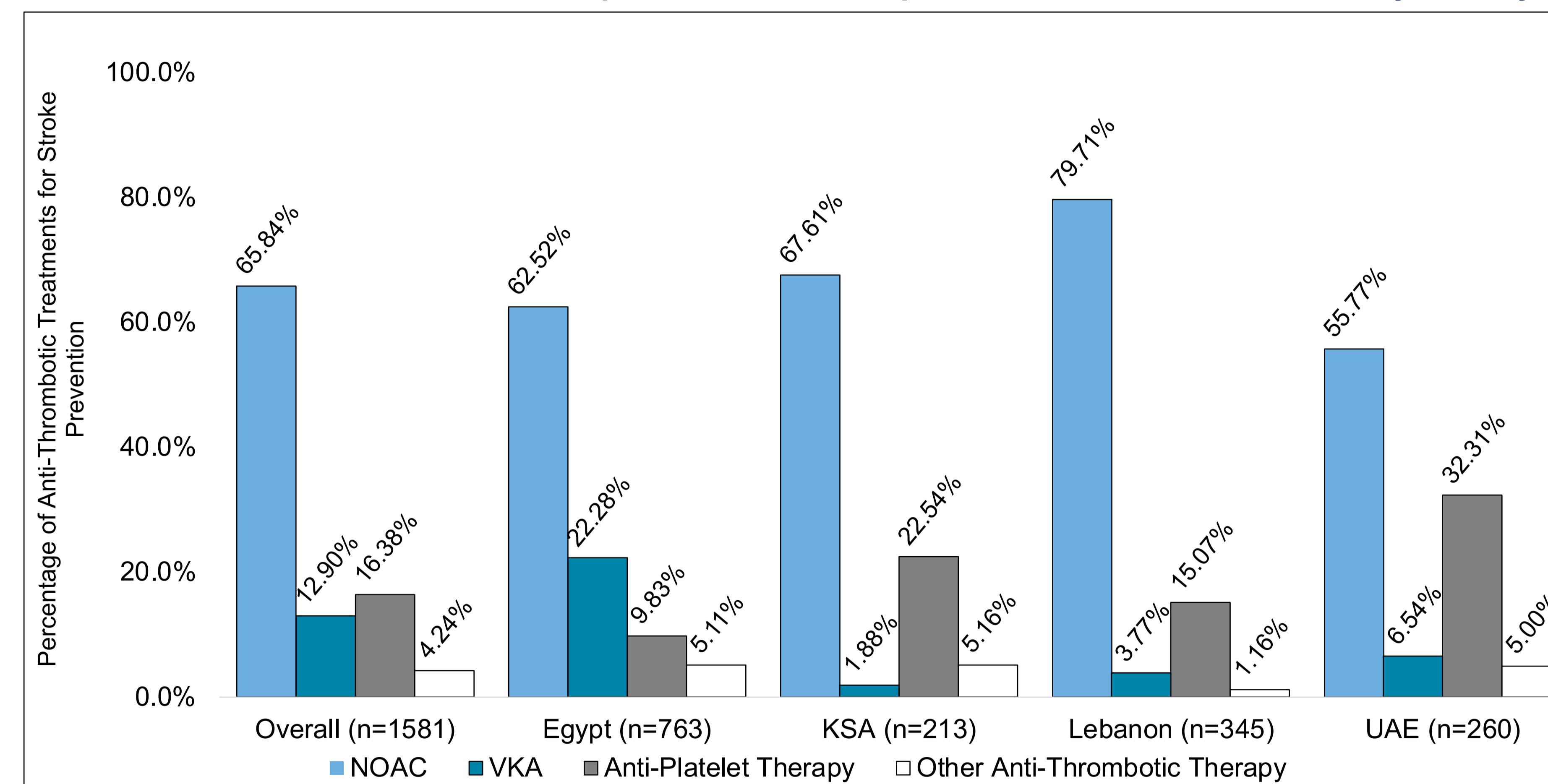
Demographic characteristics, risk factors, and comorbidities at baseline overall and by country

		Overall (N=1418)	Egypt (N=723)	KSA (N=176)	Lebanon (N=321)	UAE (N=198)
<b>Demographics</b>						
<b>Sex</b>	<b>Male, n (%)</b>	747 (52.68%)	348 (48.13%)	102 (57.95)	188 (58.57%)	109 (55.05%)
<b>Age at baseline (years)</b>	<b>Mean (SD)</b>	64.50 (14.18)	61.91 (13.53)	59.94 (14.27)	73.48 (11.35)	63.44 (14.48)
<b>BMI (categorical)</b>	<b>Obese (BMI ≥ 30.0)</b>	654 (46.98%)	350 (48.54%)	95 (56.55%)	128 (40.25%)	81 (43.78%)
<b>Atrial fibrillation characteristics</b>						
<b>Time (days) since NVAF diagnosis</b>	<b>Mean (SD)</b>	19.29 (24.24)	20.12 (25.00)	18.95 (24.49)	21.76 (24.02)	13.24 (21.10)
<b>Risk factors</b>						
<b>CHA2DS2-VASc stroke risk score</b>	<b>Mean (SD)</b>	2.65 (1.62)	2.37 (1.55)	2.62 (1.78)	3.12 (1.52)	2.95 (1.66)
<b>HAS-BLED score</b>	<b>Mean (SD)</b>	1.58 (1.15)	1.46 (1.18)	1.48 (1.17)	1.79 (0.97)	1.76 (1.19)
<b>Comorbidities*</b>						
<b>Hypertension</b>	<b>n (%)</b>	881 (62.17%)	422 (58.37%)	111 (63.43%)	209 (65.11%)	139 (70.20%)
<b>Hypercholesterolemia</b>	<b>n (%)</b>	505 (35.64%)	225 (31.12%)	59 (33.71%)	132 (41.12%)	89 (44.95%)
<b>Diabetes Mellitus</b>	<b>n (%)</b>	474 (33.43%)	216 (29.88%)	83 (47.16%)	82 (25.55%)	93 (46.97%)
<b>CAD</b>	<b>n (%)</b>	304 (21.44%)	127 (17.57%)	31 (17.61%)	87 (27.10%)	59 (29.80%)
<b>CHF/ LVD</b>	<b>n (%)</b>	262 (18.48%)	102 (14.11%)	35 (19.89%)	74 (23.05%)	51 (25.76%)

CAD, Coronary Arterial Disease; CHF, Congestive Heart Failure; CHA2DS2-VASc: CHF, hypertension, age >75 years [doubled], type 2 diabetes mellitus, previous stroke, transient ischemic attack or thromboembolism [doubled], vascular disease, age of 65-75 years, and sex; HAS-BLED: Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly; LVS, Left ventricular Dysfunction; SD, Standard deviation; KSA, Kingdom of Saudi Arabia; SD, Standard deviation; UAE, United Arab Emirates  
\*Only the most common comorbidities (≥15% among the overall study population) are presented

FIGURE 1

Antithrombotic treatment for stroke prevention in NVAF patients at baseline overall and by country



KSA, Kingdom of Saudi Arabia; NOAC, Novel oral anticoagulant; UAE, United Arab Emirates; VKA, Vitamin K antagonist  
n is the total number of treatments

## REFERENCES

- Bajpai A, Savelieva I, Camm A. Epidemiology and economic burden of atrial fibrillation. US Cardiol. 2007;4(1):14-7.
- Steger C, Pratter A, Martinek-Bregel M, Avanzini M, Valentini A, Siany J, et al. Stroke patients with atrial fibrillation have a worse prognosis than patients without: data from the Austrian Stroke registry. European heart journal. 2004;25(19):1734-40.
- Andersson T, Magnuson A, Bryngelsson I-L, Frøbert O, Henriksson KM, Edvardsson N, et al. All-cause mortality in 272 186 patients hospitalized with incident atrial fibrillation 1995–2008: a Swedish nationwide long-term case–control study. European heart journal. 2013;34(14):1061-7.
- Heidbuchel H, Verhamme P, Alings M, Antz M, Diener H-C, Hacke W, et al. Updated European Heart Rhythm Association practical guide on the use of non-vitamin-K antagonist anticoagulants in patients with non-valvular atrial fibrillation: executive summary. European heart journal. 2017;38(27):2137-49.
- Boriani G, Cimaglia P, Fantecchi E, Mantovani V, Ziacchi M, Valzania C, et al. Non-valvular atrial fibrillation: potential clinical implications of the heterogeneous definitions used in trials on new oral anticoagulants. J Cardiovasc Med (Hagerstown). 2015;16(7):491-6. Epub 2015/01/13. doi: 10.22459/jcm.0000000000000236. PubMed PMID: 25575278.
- Sobhy MA, Khoury M, Almahmeed WA, Sah J, Di Fusco M, Mardekian J, et al. The atrial fibrillation real world management registry in the middle East and Africa: design and rationale. Journal of Cardiovascular Medicine. 2020;21(9):704-10.
- Camm AJ, Amarencu P, Haas S, Hess S, Kirchhof P, Kuhl S, et al. XANTUS: a real-world, prospective, observational study of patients treated with rivaroxaban for stroke prevention in atrial fibrillation. Eur Heart J. 2016; 37(14): 1145-53

## DISCLOSURE INFORMATION

Funding: This work was funded by Pfizer.  
Authors' conflict of interest/funded support: A.H. had received honoraria from Pfizer Inc. for giving talks and workshops. M.A.S. and M.K. have no conflicts to disclose. W.A.A. is on the Pfizer Advisory board for the study. N.K. is an employee of IQVIA, which conducted the study on behalf of the sponsor. M.F.S. and S.A.K. are employees of Pfizer Inc., the study sponsor. R.D.L. has received research grants from Amgen, Bristol-Myers Squibb, GlaxoSmithKline, Pfizer, and Sanofi-Aventis; and personal fees from Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Pfizer, and Portola.