**SUPPLEMENTARY TABLES AND FIGURES**

**Predictors of intracranial haemorrhage in patients with atrial fibrillation treated with oral anticoagulants: insights from the GARFIELD-AF and ORBIT-AF registries**

**Table S1.** Potential predictors of ICH in GARFIELD-AF and ORBIT-AF registry patients

|  |  |
| --- | --- |
| Demographics | Sex |
| Age |
| Ethnicity |
| Medical history | Hypertension |
| Diabetes |
| Moderate–severe chronic kidney disease 1 |
| History of bleeding 1/history of gastrointestinal bleeding 2 |
| Congestive heart failure |
| Acute coronary syndromes |
| Vascular disease |
| Prior stroke |
| Prior TIA |
| Hypercholesterolaemia2/hyperlipidaemia3 |
| Cirrhosis1/liver disease2 |
| Hyperthyroidism |
| Hypothyroidism |
| Dementia 2/cognitive impairment or dementia 3 |
| Vital signs | Body mass index (kg/m2) |
| Heart rate (bpm) |
| Systolic blood pressure (mmHg) |
| Diastolic blood pressure (mmHg) |
| AF diagnosis | Type of atrial fibrillation |
| Treatment at diagnosis | Type of OAC (NOAC or VKA) |
| AP therapy |
| Lifestyle factors | Current smoking |
| Heavy alcohol consumption |

1 Classified according to National Kidney Foundation guidelines, stages 3–5 (estimated glomerular filtration rate <60 ml/min)

2 In GARFIELD-AF

3 In ORBIT-AF I and II

AF: atrial fibrillation; AP: antiplatelet; bpm: beats per minute; OAC: oral anticoagulant; NOAC: non-vitamin K antagonist oral anticoagulant; VKAI vitamin K antagonist; TIA: transient ischaemic attack

**Table S2.** Baseline characteristics for the GARFIELD-AF and ORBIT-AF study populations, by ICH occurrence over 2 years

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | GARFIELD-AF | | ORBIT-AF | |
| No ICH  (n = 34,148) | Any ICH  (n = 158) | No ICH  (n = 18,829) | Any ICH  (n = 126) |
| Sex, n (%) |  |  |  |  |
| Male | 18,957 (55.5) | 79 (50.0) | 10,956 (58.2) | 70 (55.6) |
| Female | 15,191 (44.5) | 79 (50.0) | 7873 (41.8) | 56 (44.4) |
| Age, median (IQR), years | 72.0 (64.0; 78.0) | 76.0 (70.0; 82.0) | 73.0 (65.0; 80.0) | 79.0 (73.0; 84.0) |
| Age, n (%), years |  |  |  |  |
| <65 | 9021 (26.4) | 18 (11.4) | 4295 (22.8) | 13 (10.3) |
| 65-69 | 5513 (16.1) | 21 (13.3) | 2927 (15.5) | 8 (6.3) |
| 70-74 | 6214 (18.2) | 27 (17.1) | 3255 (17.3) | 17 (13.5) |
| ≥75 | 13,400 (39.2) | 92 (58.2) | 8352 (44.4) | 88 (69.8) |
| Ethnicity, n (%) |  |  |  |  |
| Caucasian | 22,550 (67.7) | 107 (69.5) | 16,486 (87.6) | 113 (89.7) |
| Hispanic/Latino | 2189 (6.6) | 12 (7.8) | 901 (4.8) | 6 (4.8) |
| Asian | 7894 (23.7) | 32 (20.8) | 257 (1.4) | 1 (0.8) |
| Afro-Caribbean/Mixed/Other | 694 (2.1) | 3 (1.9) | 1176 (6.2) | 6 (4.8) |
| BMI, median (IQR), kg/m² | 27.2 (24.2; 31.1) | 26.1 (23.3; 29.8) | 29.7 (25.8; 34.7) | 28.8 (24.6; 32.6) |
| SBP, median (IQR), mmHg | 132.0 (120.0; 145.0) | 136.0 (124.0; 145.0) | 126.0 (116.0; 138.0) | 130.0 (118.0; 139.0) |
| DBP, median (IQR), mmHg | 80.0 (70.0; 89.0) | 80.0 (70.0; 90.0) | 74.0 (67.0; 80.0) | 72.0 (63.0; 80.0) |
| Pulse rate, median (IQR), bpm | 85.0 (71.0; 106.0) | 84.0 (71.5; 104.5) | 72.0 (63.0; 81.0) | 72.0 (64.0; 78.0) |
| Type of atrial fibrillation, n (%) |  |  |  |  |
| Permanent | 4867 (14.3) | 18 (11.4) | 2940 (15.6) | 32 (25.4) |
| Persistent | 5862 (17.2) | 25 (15.8) | 2882 (15.3) | 15 (11.9) |
| Paroxysmal | 8837 (25.9) | 36 (22.8) | 7492 (39.8) | 54 (42.9) |
| New onset (unclassified) | 14,582 (42.7) | 79 (50.0) | 5513 (29.3) | 25 (19.8) |
| Care specialty at diagnosis, n (%) |  |  |  |  |
| Internal medicine | 6014 (17.6) | 31 (19.6) |  |  |
| Cardiology | 22,647 (66.3) | 88 (55.7) | 15,163 (80.5) | 97 (77.0) |
| Neurology | 639 (1.9) | 2 (1.3) |  |  |
| Geriatrics | 123 (0.4) | 1 (0.6) |  |  |
| Primary care/general practice | 4725 (13.8) | 36 (22.8) |  |  |
| Care setting at diagnosis, n (%) |  |  |  |  |
| Hospital | 18,946 (55.5) | 79 (50.0) |  |  |
| Office | 11,184 (32.8) | 58 (36.7) |  |  |
| Anticoagulation clinic/ thrombosis centre | 289 (0.8) | 1 (0.6) |  |  |
| Emergency room | 3729 (10.9) | 20 (12.7) |  |  |
| Medical history, n (%) |  |  |  |  |
| Congestive heart failure | 7796 (22.8) | 32 (20.3) | 5715 (30.4) | 50 (39.7) |
| Coronary artery disease | 6727 (19.7) | 31 (19.6) | 5777 (30.7) | 57 (45.2) |
| Acute coronary syndromes | 3399 (10.0) | 18 (11.5) | 2346 (12.5) | 25 (19.8) |
| Coronary artery bypass graft | 1168 (3.5) | 8 (5.1) | 2168 (11.5) | 27 (21.4) |
| Stenting | 2269 (6.7) | 11 (7.0) | 2977 (15.8) | 30 (23.8) |
| Vascular disease 1 | 7849 (23.1) | 38 (24.4) | 6647 (35.3) | 69 (54.8) |
| Carotid occlusive disease | 1074 (3.2) | 8 (5.1) |  |  |
| Pulmonary embolism/deep Vein thrombosis | 1060 (3.1) | 3 (1.9) |  |  |
| Prior stroke | 2730 (8.0) | 22 (13.9) | 1449 (7.7) | 20 (15.9) |
| Prior TIA | 1660 (4.9) | 13 (8.3) | 1317 (7.0) | 20 (15.9) |
| Prior systemic embolism | 259 (0.8) | 1 (0.6) |  |  |
| Prior bleeding | 624 (1.8) | 3 (1.9) |  |  |
| Prior gastrointestinal bleeding |  |  | 1052 (5.6) | 15 (11.9) |
| Hypertension | 26,709 (78.4) | 126 (80.3) | 15,584 (82.8) | 112 (88.9) |
| Hypercholesterolaemia | 14,535 (43.8) | 65 (42.8) |  |  |
| Hyperlipidaemia |  |  | 12,998 (69.0) | 102 (81.0) |
| Diabetes | 7990 (23.4) | 31 (19.6) | 5342 (28.4) | 37 (29.4) |
| Cirrhosis | 162 (0.5) | 1 (0.6) |  |  |
| Liver disease |  |  | 380 (2.0) | 1 (0.8) |
| Moderate to severe CKD | 3718 (12.1) | 31 (21.5) | 380 (2.0) | 1 (0.8) |
| Dementia | 456 (1.3) | 1 (0.6) |  |  |
| Cognitive impairment/dementia |  |  | 379 (2.0) | 5 (4.0) |
| Hyperthyroidism | 594 (1.8) | 1 (0.6) | 328 (1.7) | 1 (0.8) |
| Hypothyroidism | 2099 (6.3) | 7 (4.4) | 3373 (17.9) | 28 (22.2) |
| Alcohol consumption, n (%) |  |  |  |  |
| Abstinent | 15,424 (53.5) | 76 (57.6) |  |  |
| Light | 9975 (34.6) | 49 (37.1) |  |  |
| Moderate | 2820 (9.8) | 6 (4.5) |  |  |
| Heavy | 626 (2.2) | 1 (0.8) | 677 (3.6) | 2 (2.4) |
| Smoking status, n (%) |  |  |  |  |
| Non-smoker | 20,220 (64.9) | 96 (66.2) |  |  |
| Ex-smoker | 7723 (24.8) | 34 (23.4) |  |  |
| Current smoker | 3199 (10.3) | 15 (10.3) | 1177 (6.3) | 4 (3.2) |
| OAC at baseline, n (%) |  |  |  |  |
| NOAC | 14,082 (41.2) | 41 (25.9) | 10,164 (54.0) | 46 (36.5) |
| VKA | 20,066 (58.8) | 117 (74.1) | 8665 (46.0) | 80 (63.5) |
| Concomitant AP, n (%) | 7303 (21.4) | 40 (25.3) | 6049 (32.1) | 58 (46.0) |
| CHA2DS2-VASc, median (IQR) | 3.0 (2.0; 4.0) | 4.0 (3.0; 5.0) | 4.0 (2.0; 5.0) | 5.0 (4.0; 6.0) |
| HAS-BLED, median (IQR) 2 | 1.0 (1.0; 2.0) | 2.0 (1.0; 2.0) | 1.0 (1.0; 2.0) | 2.0 (1.0; 3.0) |

1 Defined as peripheral artery disease and/or coronary artery disease

2 "Labile INR" was not included in the HAS-BLED score because it was not collected at baseline, therefore the maximum HAS-BLED score is 8 rather than 9 points

AP: anti-platelet; BMI: body mass index; INR: international normalized ratio; CKD: chronic kidney disease; DBP: diastolic blood pressure; IQR: inter-quartile range; NOAC: non- vitamin K antagonist; OAC: oral anti-coagulant; SBP: systolic blood pressure**;** TIA: transient ischaemic attack; VKA: vitamin K antagonist

**Table S3.** ICH event rates per 100 person-years calculated over two-year data

|  |  |  |  |
| --- | --- | --- | --- |
| Registry | No. Events |  | Rate (95% CI) |
| GARFIELD-AF (N = 34,306) | 158 |  | 0.25 (0.21–0.29) |
| ORBIT-AF (N = 18,955) | 126 |  | 0.46 (0.39–0.55) |
| Overall (N = 53,261) | 284 |  | 0.31 (0.28–0.35) |
|  |  |  |  |

**Table S4.** Site of bleed for 158 GARFIELD-AF patients who experienced ICH within 2 years

|  |  |
| --- | --- |
| Site of ICH | n (%) |
| Intracerebral | 48 (30.4) |
| Subarachnoid | 11 (7.0) |
| Intraventricular | 9 (5.7) |
| Subdural | 72 (45.6) |
| Epidural | 6 (3.8) |
| Unknown | 12 (7.6) |

**Table S5.** Distribution of ICH in the 158 GARFIELD-AF ICH patients.

|  |  |
| --- | --- |
| No. ICH in a single patient | n (%) |
| 1 | 149 (94.3) |
| 2 | 8 (5.1) |
| 3 | 1 (0.6) |

# **Table S6**. Intracranial hemorrhage event rates (per 100 person-years) within two years of follow-up by baseline treatment and CKD stage.

|  |  |  |
| --- | --- | --- |
| **Baseline treatment**  CKD stage | **Events** | **Rate (95% CI)** |
|  |  |  |
| **Overall** |  |  |
| None to Mild CKD | 199 | 0.26 (0.23-0.30) |
| Moderate to severe CKD | 85 | 0.52 (0.42-0.64) |
|  |  |  |
| **NOAC** |  |  |
| None to Mild CKD | 66 | 0.20 (0.15-0.25) |
| Moderate to severe CKD | 21 | 0.34 (0.22-0.53) |
|  |  |  |
| **VKA** |  |  |
| None to Mild CKD | 133 | 0.32 (0.27-0.38) |
| Moderate to severe CKD | 64 | 0.63 (0.49-0.80) |
|  |  |  |

**Table S7.** Predictors of major bleeding: Wald chi-square, p-values, and hazard ratios (HRs) for components of the ICH model

|  |  |  |  |
| --- | --- | --- | --- |
| ICH model component | Chi-square | p-value | HR (95% CI) |
|  |  |  |  |
| Age 1 | 124 | <0.0001 | 1.18 (1.14–1.21) |
| Prior stroke/TIA | 9 | 0.0024 | 1.23 (1.08–1.41) |
| AP therapy (ref.: no AP) | 60 | <0.0001 | 1.57 (1.40–1.76) |
| Moderate-to-severe CKD | 136 | <0.0001 | 1.95 (1.75–2.19) |
| Vascular disease 2 | 61 | <0.0001 | 1.57 (1.40–1.75) |
| VKA treatment (ref.: NOAC treatment) | 8 | 0.0056 | 1.16 (1.05-1.30) |

1 HRs with 95% CI based on incremental units of "5"

2 Defined as peripheral artery disease and/or coronary artery disease

C-statistic: 0.68 (95% CI, 0.67–0.70)

**Table S8.** Distribution of ICH model predictors by registry

|  |  |  |
| --- | --- | --- |
| **ICH model predictors** | **GARFIELD-AF** | **ORBIT-AF** |
| Moderate to severe CKD, n (%) | 4154 (12.1) | 6027 (31.8) |
| Age, mean (SD), years | 70.6 (10.8) | 72.0 (10.7) |
| Vascular disease, n (%) | 7919 (23.1) | 6716 (35.4) |
| AP treatment, n (%) | 7343 (21.4) | 6107 (32.2) |
| Prior stroke/TIA, n (%) | 4093 (11.9) | 2529 (13.3) |
| VKA treatment, n (%) | 20183 (58.8) | 8745 (46.1) |

# **Table S9**. Methods for calculation of ICH risk, according to the ICH predictive model

# 1. Model equations for one- and two-year predicted events

One-year predicted probability= 100\*(1-(0. 9987280927^(exp(**0.52880**\*prior stroke/TIA + **0.47827**\*VKA + **0.30718**\*Treatment with AP + **0.29362**\*moderate or severe CKD + **0.22608**\*vascular disease + **0.04591**\*(age-65) ))))

Two-year predicted probability = 100\*(1-(0.9978303850^(exp(**0.52880**\*prior stroke/TIA + **0.47827**\*VKA + **0.30718**\*Treatment with AP + **0.29362**\*moderate or severe CKD + **0.22608**\*vascular disease + **0.04591**\*(age-65) ))))

# 2. Table for calculation of the ICH risk score and nomogram for the predicted probability of ICH over two years by total points

|  |  |  |  |
| --- | --- | --- | --- |
| **Risk factor** | **Category** | **Points** | **Score** |
| Baseline risk | Prior stroke/TIA | 4 |  |
|  | Moderate to severe CKD | 2 |  |
|  | Vascular disease | 2 |  |
| OAC Treatment | NOAC | 0 |  |
|  | VKA | 3 |  |
| AP Treatment | No | 0 |  |
|  | Yes | 2 |  |
| Age | <45 | 0 |  |
|  | 45-54 | 3 |  |
|  | 55-64 | 7 |  |
|  | 65-74 | 10 |  |
|  | 75-84 | 13 |  |
|  | ≥85 | 17 |  |
| **Total score** |  |  |  |

**Examples:**

|  |  |  |
| --- | --- | --- |
| **Patient 1 (low risk)** | **Patient 2 (medium risk)** | **Patient 3 (high risk)** |
|  |  |  |
| *Age:* 62 | *Age:* 76 | *Age:* 88 |
| *OAC treatment:* NOAC | *OAC treatment:* VKA | *OAC treatment:* VKA |
| *AP treatment:* No | *AP treatment:* No | *AP treatment:* Yes |
| *Baseline risk factors:* None | *Baseline risk factors:* None | *Baseline risk factors:* Vascular disease, Prior stroke/TIA |
|  |  |  |
| **Total points: 7** | **Total points: 16** | **Total points: 28** |
| **ICH probability: 0.23%** | **ICH probability: 0.78%** | **ICH probability: 4.0%** |
|  |  |  |

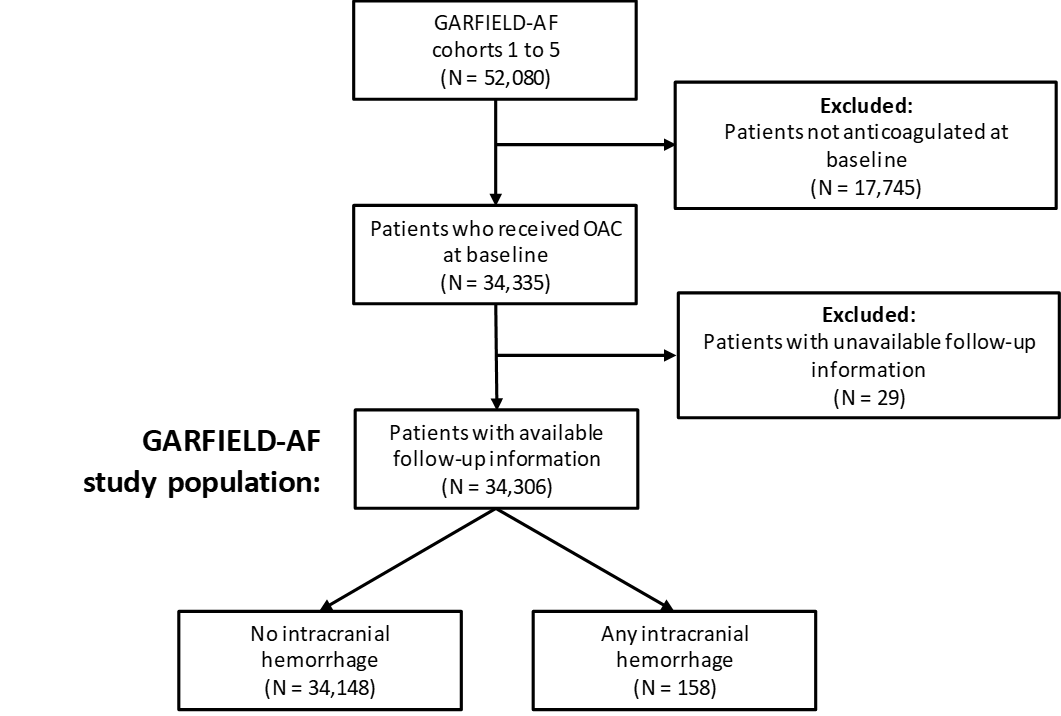
**Table S10. Baseline characteristics of the Danish Validation Cohort**

|  |  |
| --- | --- |
| **Variable, n (%)** | **Total population**  **(n=39,929)** |
| Age, median (IQR) | 74.74 (67.27, 81.82) |
| Male | 22496 (56.3) |
| Diabetes | 6077 (15.2) |
| Ischemic stroke/TIA | 6021 (15.1) |
| Ischemic stroke/TIA/hemorrhagic stroke | 6179 (15.5) |
| Systemic embolism | 237 (0.6) |
| Cancer | 4543 (11.4) |
| Chronic obstructive pulmonary disease | 4225 (10.6) |
| Bleeding | 4049 (10.1) |
| Chronic kidney disease | 1573 (3.9) |
| Hemorrhagic stroke | 281 (0.7) |
| Heart failure | 7431 (18.6) |
| Ischemic heart disease | 5664 (14.2) |
| Non-vitamin K antagonist oral anticoagulants | 15753 (39.5) |
| Vitamin K antagonists | 25156 (63.0) |
| Peripheral artery disease | 1127 (2.8) |
| Sleep dyspnea | 423 (1.1) |
| Liver disease | 374 (0.9) |
| Venous thromboembolism | 1406 (3.5) |
| Dipyridamole | 1093 (2.7) |
| Hypertension | 27964 (70.0) |
| NSAID | 5665 (14.2) |
| ASA | 13264 (33.2) |
| Adenosine diphosphate inhibitor | 2910 (7.3) |
| Pulmonary embolism | 1456 (3.6) |
| PCI | 2728 (6.8) |
| CABG | 1490 (3.7) |
| Vascular disease (ischemic heart disease and/or peripheral artery disease) | 6441 (16.1) |
| Garfield ICH, median (IQR) | 0.05 [0.03, 0.08] |
| OAC | 39929 (100.0%) |
| CHA2DS2-VASc, median (IQR) | 3.00 [2.00, 4.00] |
| HASBLED, median (IQR) | 2.00 [1.00, 3.00] |

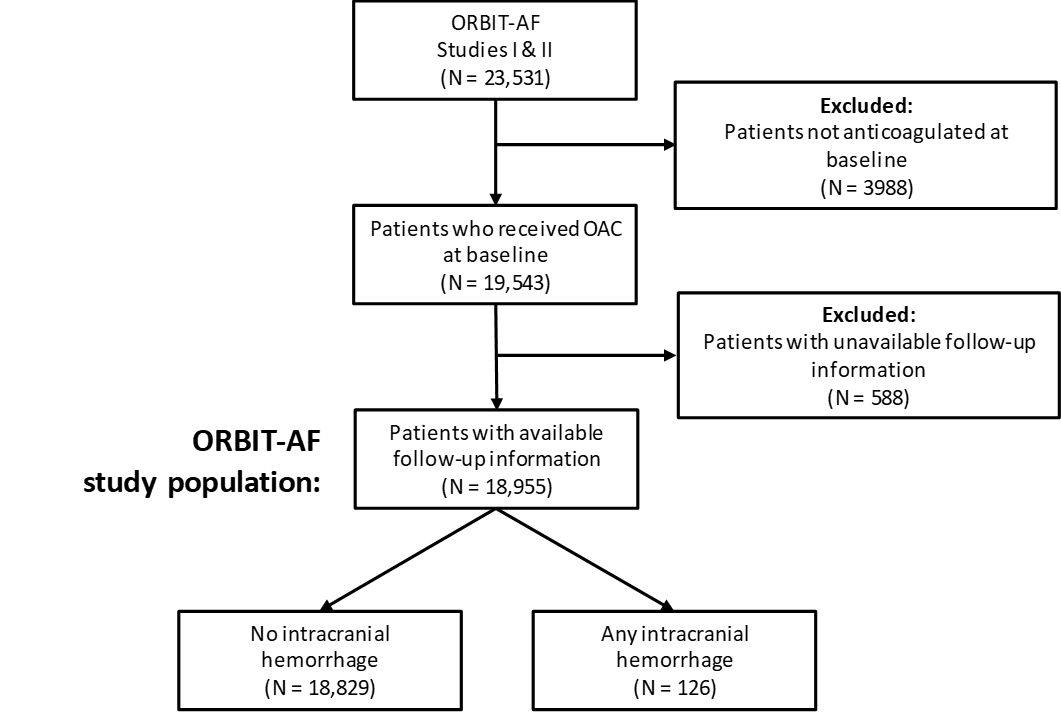
ASA: acetylsalicylic acid (aspirin); CABG: coronary artery bypass graft; NSAID: non-steroidal anti-inflammatory drugs; PCI: percutaneous coronary intervention**;** TIA: transient ischaemic attack **Figure S1.** Study population selection and intracranial haemorrhage (ICH) occurrence



**Figure S2.** Flowchart for selection of GARFIELD-AF study population.



**Figure S3.** Flowchart for selection of ORBIT-AF study population.



**Figure S4.** External validation via the Danish Cohort

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C-statistic: 0.65 (0.62 – 0.68)

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