

persistence levels with all OACs but with advantage of NOACs. Persistence with both rivaroxaban and apixaban was better than dabigatran.

#### P4803

##### Prior antithrombotic therapy: a snapshot of 17,769 patients from the global edoxaban treatment in routine clinical practice in patients with non-valvular atrial fibrillation programme (global ETNA-AF)

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**Background:** Edoxaban has been approved for stroke prevention in patients with atrial fibrillation based on its effectiveness and superior safety compared to warfarin in the controlled ENGAGE AF-TIMI 48 trial. The global ETNA-AF programme was initiated to evaluate the effectiveness and safety of edoxaban in patients under real-life conditions.

**Purpose and methods:** The global ETNA-AF programme combines information from 3 separate registries conducted in Europe, East Asia, and Japan, and will describe the use of edoxaban in routine clinical care, including the safety and efficacy of edoxaban. Data were harmonised, transformed, and integrated into a single database. A total of about 27,000 ETNA-AF patients will be included in the ETNA-AF registries and followed for  $\geq 2$  years. We report a snapshot analysis of 17,769 patients focusing on antithrombotic therapy before initiation of edoxaban. At the ESC Congress, data from all available patients will be presented.

**Results:** Of the patients participating in global ETNA-AF, 12855/17769 (72.3%) patients were anticoagulation-naive, 4914/17769 (27.7%) were on oral anticoagulation therapy before edoxaban was initiated, 2806/17769 (15.8%) were on a vitamin K antagonist (VKA), and 2108/17769 (11.8%) were on other non-VKA oral anticoagulants (NOACs). Patients from Korea/Taiwan have the highest percentages of previous use for both a VKA (370/2046 [18.1%]) and other NOACs (500/2046 [24.4%]) followed by Japan (VKA:1019/7227 [14.1%], NOAC:860/7227 [11.9%]), and Europe (VKA:1417/8496 [16.7%], NOAC:748/8496 [8.8%]). Antiplatelet use, mainly aspirin (A) and clopidogrel (C), was highest in Korea/Taiwan (A:281/2046 [13.7%], C:82/2046 [4.0%]) followed by Europe (A:1132/8496 [13.3%], C:189/8496 [2.2%]), and Japan (A:202/7227 [2.8%], C:35/7227 [0.5%]). Table 1 shows antithrombotic therapy before study entry relative to the edoxaban dose at baseline of ETNA-AF.

**Conclusion:** More than 2/3 of patients treated with edoxaban in the global ETNA-AF programme were not on an anticoagulant before starting edoxaban. More than 40% of the anticoagulated patients were on another NOAC before starting edoxaban.

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#### P4804

##### Oral anticoagulation continuation vs. discontinuation after catheter-ablation of paroxysmal atrial fibrillation - incidence of cerebral insults and severe hemorrhagic complications

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**Introduction:** Current guidelines recommend continuation of oral anticoagulation for patients after successful catheter-ablation of atrial fibrillation. Only few data is available on the incidence of cerebral insults and severe hemorrhagic complications in patients with this postinterventional treatment.

**Purpose:** The aim of this study was to investigate the incidence of cerebral insults and severe hemorrhagic complications after catheter-ablation within a large patient cohort with continued vs. discontinued oral anticoagulation after successful catheter ablation of atrial fibrillation.

**Methods:** Between the years 2011 and 2016 a total amount of n=1286 patients suffering from paroxysmal atrial fibrillation underwent pulmonary vein isolation and regular follow-up visits at the hospital after 3, 6 and subsequently every 6

months. Freedom from AF was assessed using 2 consecutive 7 day Holter ECGs and patients with a successful ablation could stop oral anticoagulants 6 months after ablation if no prior stroke/TIA were present. In subsequent follow-up examinations the incidence of cerebral insults, severe hemorrhagic complications, medication intake and AF relapse were documented.

**Results:** Table 1 shows the baseline characteristics of the patients. The mean follow-up period was 806±601 days. 70.1% of the patients were free of AF during follow-up after the procedure. The last follow-up examination revealed that n=621 patients (48%) were still taking the oral anticoagulants, while n=665 patients (52%) had discontinued the treatment. Of the patients who stopped the use of oral anticoagulants, only 3.3% did so against medical advice.

Within the patients who discontinued anticoagulation, the incidence of cerebral insults was 0.60%. The incidence of severe hemorrhagic complication was 1%. Patients still taking the oral anticoagulants showed an incidence of cerebral insults of 1.93% and an incidence of severe hemorrhagic complications of 8%. The results were statistically significant (p<0.01).

	OAC YES, N=621	OAC NO, N=665	p-value
Age [years]	67.1±10.3	60.4±11.4	<0.02
Male [%]	52%	69%	<0.01
CHADSVASC	2.38±1.4	1.46±1.1	<0.01

**Conclusion:** In this study, the discontinuation of oral anticoagulation after thorough assessment of successful catheter-ablation showed no higher incidence of cerebral insults or severe hemorrhagic complications. Nevertheless, it must be considered, that the CHADSVASC-score was significantly lower in the group of patients who stopped the postinterventional treatment.

#### P4805

##### A new score for assessing bleeding risk in patients with atrial fibrillation treated with NOACs

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**Background:** Atrial fibrillation (AF) significantly increases the risk of embolic stroke and death. Treatment with oral anticoagulants (OAC) effectively reduces risk of stroke, but this effect comes at a cost of significantly increased risk of bleeding. Non-vitamin K oral anticoagulants (NOACs) are gradually replacing vitamin K antagonists as the drugs of choice. Studies on risk factors for bleeding have mainly been performed on warfarin-treated patients. In the current era, information is needed on bleeding risk factors specifically for patients on NOACs.

**Purpose:** The aim of this study was to identify risk factors for bleeding in patients with atrial fibrillation being treated with NOACs, and to create a simple bedside tool to assess bleeding risk in these patients.

**Methods:** Using nationwide registries (Norwegian Patient Registry and Norwegian Prescription Database), we identified AF patients with a first prescription of a NOAC between January 2013 and June 2015. Patients were followed until discontinuation or switching of oral anticoagulants, death, or end of follow-up (June 30, 2015). The primary endpoint was major or clinically relevant non-major (CRNM) bleeding. Cox proportional hazards analyses were used to identify risk factors for bleeding, and a bleeding score was developed based on the ten strongest risk factors.

**Results:** A total of 21 248 patients were included in the cohort; 7925 were treated with dabigatran, 6817 with rivaroxaban, and 6506 with apixaban. The median age was 73 years and 57.4% of patients were male. After a median follow-up time of 183 days, 1257 (5.9%) patients experienced a major or CRNM bleeding. The strongest prediction model included the variables age, male sex, history of stroke/TIA, history of bleeding, history of anaemia, hypertension, heart failure, non-bleeding related hospitalisation within the last 12 months, chronic kidney disease, and chronic obstructive pulmonary disease, and showed good discriminative ability, with a Harrell's c - index of 0.68. A bleeding risk score was then created with weights proportional to the model coefficients. From our cohort we also calculated a modified HAS-BLED score, which achieved a c - index of 0.59. A simplified score was finally derived from the full score, including only age, history of bleeding, and non-bleeding related hospitalisation within the last 12 months, that reached a Harrell's c - index of 0.66.

**Conclusions:** In this nationwide cohort study of real-life AF patients being prescribed NOACs, a bleeding risk score was created that showed a high c - index, requiring no blood sampling or imaging for its calculation. The simplified version

Abstract P4803 – Table 1

	Global		Europe		Japan		Korea/Taiwan	
	60 mg (n=9516)	30 mg (n=8253)	60 mg (n=6550)	30 mg (n=1946)	60 mg (n=1955)	30 mg (n=5272)	60 mg (n=1011)	30 mg (n=1035)
Oral antiplatelets, n (%)	1300 (13.7)	721 (8.7)	1038 (15.8)	329 (16.9)	80 (4.1)	192 (3.6)	182 (18.0)	200 (19.3)
ASA, n/N (%)	1070/1300 (82.3)	575/721 (75.5)	873/1038 (84.1)	259/329 (78.7)	58/80 (72.6)	144/192 (75.0)	139/182 (76.4)	142/200 (71.0)
Clopidogrel, n/N (%)	160/1300 (12.8)	139/721 (19.3)	130/1038 (12.5)	59/329 (17.9)	6/80 (7.5)	29/192 (15.1)	30/182 (16.5)	52/200 (26.0)
VKA, n (%)	1507 (15.8)	1299 (15.7)	1071 (16.4)	346 (17.8)	249 (12.7)	770 (14.6)	187 (18.5)	183 (17.7)
NOAC, n (%)	983 (10.3)	1125 (13.6)	496 (7.6)	252 (12.9)	226 (11.6)	634 (12.0)	261 (25.8)	239 (23.1)

ASA, acetylsalicylic acid.