among NOACs and vitamin K antagonist (VKA) for preventing the primary composite end point (stroke and systemic embolism [SE]) and major bleeding (MB). Secondary endpoints included all-cause mortality, stroke, myocardial infarction and SE.

Results: We identified 8 phase 3 RCTs for primary analyses and additional 3 phase 2 RCTs for sensitivity analyses. Efficacy of each NOAC was similar in terms of primary composite endpoints (odds ratios [ORs] for VKA: A.0.79; D伏5.77; R.0.86) after the adjustment for the bias from open label studies (Figure). A had significantly fewer MB than other NOACs (ORs 0.64-0.74) although the difference in benefit of A was different from other NOACs. Efficacy and safety of A, primarily assessed by an open label study, were overestimated. All NOACs were similar in reducing secondary endpoints except that R had significantly fewer SE compared to A (OR 0.3).

Conclusions: All NOACs were generally similar in terms of efficacy. Differences in study designs and endpoint definitions are important when comparing NOACs.

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Predictors of left atrial appendage thrombosis in patients with atrial fibrillation
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Purpose: To evaluate hemodynamic, haemostatic and genetic predictors of thrombus formation in left atrial appendage (LAA) in patients with permanent atrial fibrillation.

Methods: Studied 200 patients with ischemic heart disease and permanent atrial fibrillation (mean age – 62.4±6.8 years). All the patients were divided into three groups: 1 group comprised 100 patients with LAA thrombosis and 2 – 100 patients without LAA thrombosis according to transesophageal echocardiography. All the patients also underwent transthoracic echocardiography. We evaluated haemostatic indicators such as thrombin activatable fibrinogen in-hibitor (TAI), soluble fibrin monomer complexes, antithrombin, fibrinogen and also genetic polymorphisms of cytochrome P-450 CYP, vitamin K epoxide reduc-
tase complex subunit 1 (VKORC1) C1173T, G3730A and plasminogen activator inhibitor (PAI-1) -4G allele.

Results: In patients with LAA thrombosis the mean level of LAA peak emptying flow velocity was 35% lower (p=0.002) and mean TAI level was 16.2% higher (p=0.03) than in patients without LAA thrombosis. Patients with LAA thrombo-
sis had more severe spontaneous echocontrast (SEC) than patients without LAA thrombosis (p=0.01). Patients of the 1 group had CC genotype of VKORC1 35% more frequently (p=0.001) and allele 4G of PAI-1 18% more frequently (p=0.02) than patients of the 2 group. The odds ratio for LAA thrombosis in patients with LAA peak emptying flow velocity less than 34 cm/s was 5.6 (95% CI: 1.4-21, p=0.01), with severe SEC – 7.2 (95% CI: 1.6-32, p=0.01), with TAI levels more than 24% (6.7 (95% CI: 1.7-26, p=0.006). The odds ratio for LAA thrombosis in patients with CC genotype of VKORC1 C1173T was 5.4 (95% CI: 1.5-19.3, p=0.01) and with 4G allele of PAI-1 – 6.9 (95% CI: 1.2-32.4, p=0.02).

Conclusions: LAA peak emptying flow velocity less than 34 cm/s, SEC, TAI levels more than 245%, the presence of CC genotype of VKORC1 C1173T and 4G allele of PAI-1 are powerful predictors of LAA thrombosis in patients with permanent atrial fibrillation.

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Incidence of thromboembolic events in patients with atrial fibrillation in Japan: one-year follow-up from the Fushimi AF registry
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Purpose: Atrial fibrillation (AF) is a common arrhythmic disorder among the el-
derly, and is increasing significantly as the population ages (reportedly 0.6% of total population in Japan). AF increases the risk of thromboembolism and death. We investigated the incidence of thromboembolic events in a large Japanese co-
hort of AF patients under current real-world clinical settings.

Methods: The Fushimi AF Registry, a community-based prospective survey, was designed to enroll all of the AF patients in Fushimi-ku, Kyoto, Japan. Fushimi-ku is one of the 4 districts of the Japanese AF patients. Underuse or low-intensity control of anticoagulants may result in the insufficient prevention of thromboembolic events and the relatively low incidence of bleeding events.

Results: We identified 8 phase 3 RCTs for primary analyses and additional 3

secondary endpoints included all-cause mortality, stroke, myocardial infarction and SE. We classified procedures as major if they required general anaes-
thesia or if the risk of significant post-operative bleeding was considered high. Procedures were classified according to ISTH criteria. Adherence to Mediterranean diet was evaluated by administration of a short dietary questionnaire.

Results: Mean age was 73.6 years and 59% patients were male. Time in ther-
apeutic INR range (TTR) was 63.8% in patients without bleeding and 64.8% (p=0.68) in those with bleeding. Significant differences between groups consisted in history of MI/CHD (p=0.039), HAS BLED score (p=0.002) and vitamin E lev-
els (p<0.001). Bleeding events occurred in 92 (16.2%) patients (73 minor and 19 major bleedings). Cerebral bleeding occurred in 4 patients (0.70%). The overall incidence rate of any bleeding event was 9.2/100 person-years. Higher vitamin E serum levels were found in patients who experienced bleeding compared to those who did not (5.27±1.93 vs. 4.48±1.97 μmol/mL; p<0.001), and a progressive increase from patients without bleeding to those with minor (5.16±1.91 μmol/mL; p=0.006) and major bleedings (5.72±2.0 μmol/mL; p=0.008) was observed. A Cox proportional hazard model demonstrated that vi-
tamin E serum and HAS BLED score independently predicted bleeding events (p=0.004 and p=0.001 respectively). Vitamin E serum levels linearly increased in patients with an higher adherence to Mediterranean diet, although no differences in Mediterranean diet adherence were observed in patients with or without hem-
condrome. Among dietary elements analyzed, olive oil consumption is the only component significantly associated to vitamin e level.

Conclusions: In NVAF serum vitamin E levels progressively increase from pa-
tients without to those with minor and major bleedings. Vitamin E serum levels can be a useful tool to stratify bleeding risk in patients receiving OAT.

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Use of apixaban and warfarin in patients undergoing invasive procedures: insights from ARISTOTLE

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Purpose: For AF pts taking warfarin to prevent stroke, the risk of stroke or systemic embolism associated with stopping warfarin for invasive procedures is thought to be low. Little is known about apixaban use in pts undergoing invasive procedures.

Methods: Using data from 18,201 pts in ARISTOTLE (median follow-up: 1.8 yrs), we described the most common invasive procedures, the use of bridging therapy, the risk of stroke and major bleeding during the 30 days following invasive procedures. We classified procedures as major if they required general anaes-
thesia or if the risk of significant post-operative bleeding was considered high. Procedures were also classified as emergent or non-emergent by investigators.

Results: There were 11,417 invasive procedures in 6162 pts. Of these, 477
none have considered impact of eGFR on bleeding. We therefore conducted the first long-term prospective study of eGFR and stroke/TE, mortality and bleeding in an AF population, unrestricted by age or comorbidity.

Methods: Patients diagnosed with non-valvular AF (NVAF) and available eGFR data in a four-hospital institution between 2000 and 2010 were identified. The study population was stratified into five categories according to eGFR (in mL/min/1.73 m²): <30, 30-59, 60-89, 90-119, and ≥120, analysing risk factors, as well as incidence and survival for all-cause mortality, bleeding and stroke/TE.

Results: Of 8962 eligible individuals, 5912 (66.0%) had NVAF and available eGFR data. In non-anticoagulated and anticoagulated individuals, rates of stroke/TE were 7.4% (95% CI 3.6-8.6) and 7.2 (6.3-8.2) per 1000 person years, respectively. Incidence rates of all-cause mortality were 13.4 (12.0-15.0) and 9.4 (8.9-10.5), respectively, and of major bleeding were 6.2 (5.2-7.3) and 9.0 (8.0-10.1) per 1000 person years, respectively. Rates of all events increased with decreasing eGFR, regardless of OAC, and rates of stroke/TE were lower in individuals receiving OAC.

Conclusions: The benefit of ischemic stroke reduction is balanced against the increased risk of haemorrhagic stroke amongst patients with renal impairment, the net clinical benefit (NCB) could be clearly positive in favour of OAC use: for individuals with eGFR<30, NCB=2.06 (95% CI 1.40-2.76), whilst for eGFR ≥30, NCB=6.69 (3.27-12.78).

At 10 years, in individuals with eGFR >60 mL/min/1.73m² and with eGFR <30 mL/min/1.73m², the overall rates of stroke/TE were 17.7% and 30.7%, respectively. Overall rates of all-cause mortality were 21.7% and 66.8%, and of bleeding were 21.9% and 47.1%, respectively.

Conclusion: Renal impairment is a poor prognostic indicator of stroke/TE, bleeding and mortality in all individuals in categories of renal function as measured by eGFR. The NCB balancing ischaemic stroke against serious bleeding was positive, in favour of OAC use amongst patients with renal impairment.

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Oral anticoagulant therapy management after successful atrial fibrillation ablation

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Purpose: Transcatheter ablation (TA) has emerged as a promising therapeutic strategy for atrial fibrillation (AF), but the long-term use of oral anticoagulation therapy (OAT) after a successful procedure is still debatable. The aim of our study was to evaluate the long-term incidence of cerebral thromboembolic (TE) and haemorrhagic events according to the OAT strategy used in patients with AF undergoing TA.

Methods: A total of 766 (612 males 79%, mean age 57±11 years) patients were included in this non-randomized, prospective observational study. The individual TE/hemorrhagic risk profile was evaluated by CHADS2, CHA2DS2-VASc and HASBLED scores. OAT was discontinued in patients with CHA2DS2-VASc ≥2 or HASBLED score ≥3. The incidence of major bleedings was assessed by treatment group during 30 days following a bleed.

Results: Of 267 patients (34.9%, mean age 57±11 years) patients were in the On-OAT group (p=0.150). Overall, 6 (2.2%) TE events occurred in the On-OAT group and 5 (1.0%) in the Off-OAT group (p=0.145). In all cases AF recurrence were recorded at the hospital admission. CHADS2 and CHA2DS2-VASc scores ≥2 were statistically significant predictors of TE events (p=0.047 and p=0.020 respectively). Seven major hemorrhagic events occurred, all of them amongst On-OAT patients (30±7±26%). A HASBLED score ≥2 was associated with a higher incidence of hemorrhagic events (p=0.038). The overall incidence of TE/hemorrhagic events was 0.29 per 100 patient years.

Conclusion: The overall incidence of TE events in this cohort of patients with AF undergoing TA was lower than in the general anticoagulated AF population. However considering the unpredictable nature of TE events, the routine use of CHADS2, CHA2DS2-VASc and HASBLED scores should be recommended to guide decision about continuation or withdrawal of OAT following TA. Interestingly, all the TE events occurred during AF recurrences. Whether sinus rhythm mainte-