IMPACT-Afib trial: Implementation of Stroke Prevention in Atrial Fibrillation

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ESC Congress- Hotline Sessions

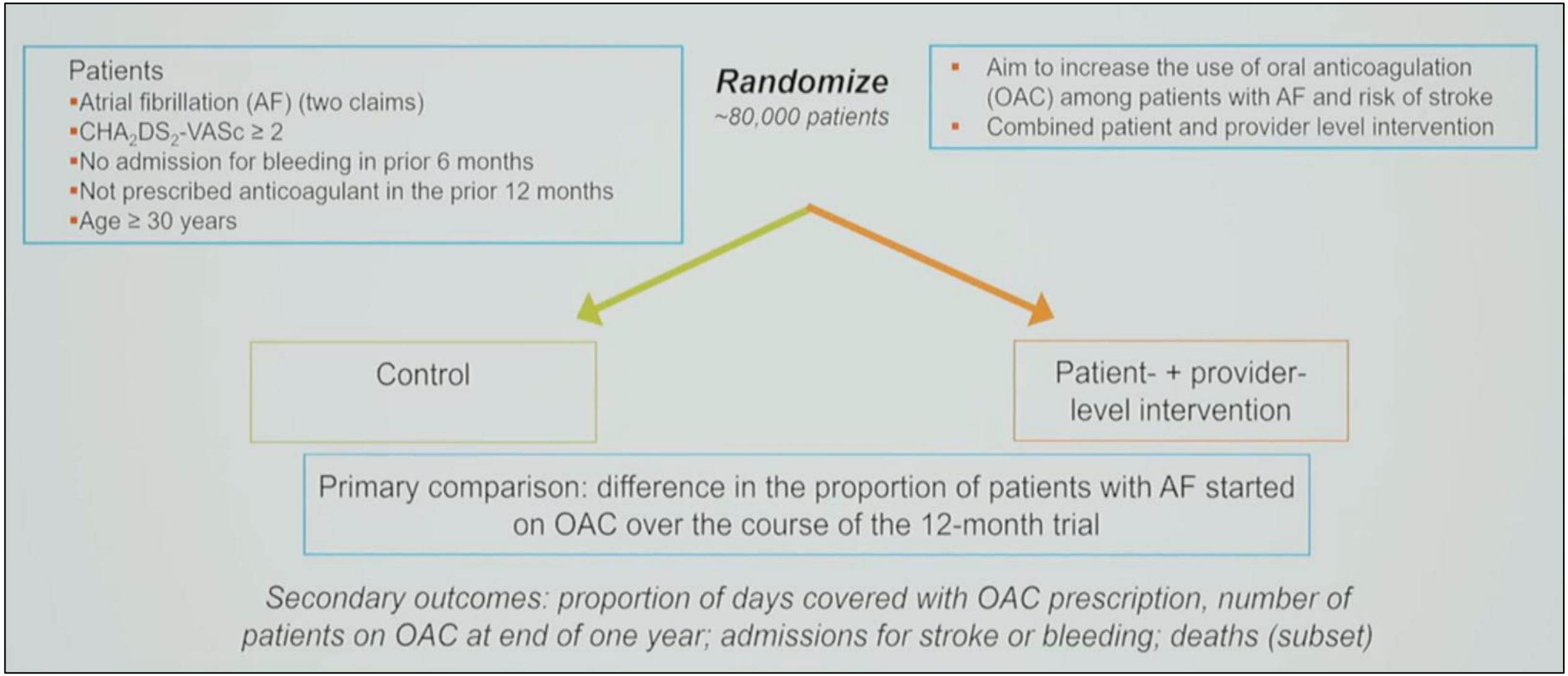
Background and AIM of the study

Oral anticoagulants (OACs) are underused for stroke prevention in patients with atrial fibrillation (AF).

AIM of the study

To evaluate if an educational intervention targeted towards the patient and healthcare provider help to increase OAC initiation

Study design



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Methods

- US Food and Drug Administration-funded prospective trial.
- Patient selection and follow-up were via the databases of five insurance companies.
- Inclusion criteria: patients aged ≥30 years with AF and a guideline-based indication for OAC (CHA_2DS_2-VASc score of ≥2).
- Exclusion criteria: patients been prescribed an anticoagulant in the prior 12 months or been admitted to hospital for bleeding in the prior 6 months.

Education mailing

How can I keep myself safe from bleeding and falls?

(As with other medications, there is a risk of experiencing side effects while taking anticoagulants. The main side effect is that you can bleed too easily.)

- Use a soft bristle toothbrush and waxed dental floss
- Use an electric razor to shave
- Be careful with sharp objects: toothpicks, knives, tools, scissors, etc.
- Wear shoes or non-skid slippers at all times
- Avoid nonsteroidal anti-inflammatory drugs like ibuprofen, naproxen, etc.
- Be careful when trimming toenails or callouses
- Avoid activities that increase risk of falls or involve hard contact, such as contact sports

Is it OK to take an anticoagulant medication if I have had bleeding? What if I fall?

- If you are at high risk for bleeding, the use of an anticoagulant medication depends on whether the benefit of preventing a stroke is more important than the risk of bleeding. Talk with your doctor about your risk.
- The benefits of preventing stroke outweigh the risk of bleeding for many people who might fall.

If I have bleeding, is there something to reverse the effect of anticoagulant medications? An antidote?

- Yes, there are antidotes for warfarin and Pradaxa
- Reversal drugs are in development for other anticoagulant medications
- There is no antidote for aspirin

Will an anticoagulant medicine interact with other medicines or foods?

- Warfarin interacts with foods that are high in vitamin K
  - You should ask your doctor or pharmacist for a list of food interactions
- Xarelto should be taken with food to help your body absorb the medicine

Talk with your doctor or pharmacist if you have questions about any medications or foods that might affect your anticoagulant medication, including nonprescription medicines, vitamins, and herbal supplements.

Am I at risk for stroke?

- The CHA_2DS_2-VASc calculates stroke risk for patients with atrial fibrillation.
- Complete the following CHA_2DS_2-VASc calculator to determine your personal risk.
- If you have AFib and a CHA_2DS_2-VASc score of 2 or greater, you have an increased risk of stroke.

CHA_2DS_2-VASc RISK SCORE	If yes, add points
Do you have congestive heart failure?	+1
Do you have high blood pressure or are you taking blood pressure medication(s)?	+1
Are you between 65–74 years of age?	+1
Are you 75 years old or older?	+2
Do you have diabetes?	+1
Have you ever had a stroke or TIA (mini-stroke)	+2
Have you ever had vascular disease (bypass surgery, heart attack, peripheral artery disease, or aortic plaque)?	+1
Are you female?	+1
MY TOTAL	

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Patient baseline characteristics

	Early Intervention N=23,546	Delayed Intervention N=23,787
Age (years), Mean	77.8 (9.7)	77.9 (9.7)
≥ 75 years old	14,589 (62.0%)	14,688 (61.7%)
Female	11,262 (47.8%)	11,162 (46.9%)
CHA_2DS_2-VASc score, Mean	4.53 (1.68)	4.50 (1.65)
ATRIA Score ≥ 5	11,165 (47.4%)	11,239 (47.3%)
History of Hospitalization for Bleeding	4,409 (18.7%)	4,481 (18.8%)

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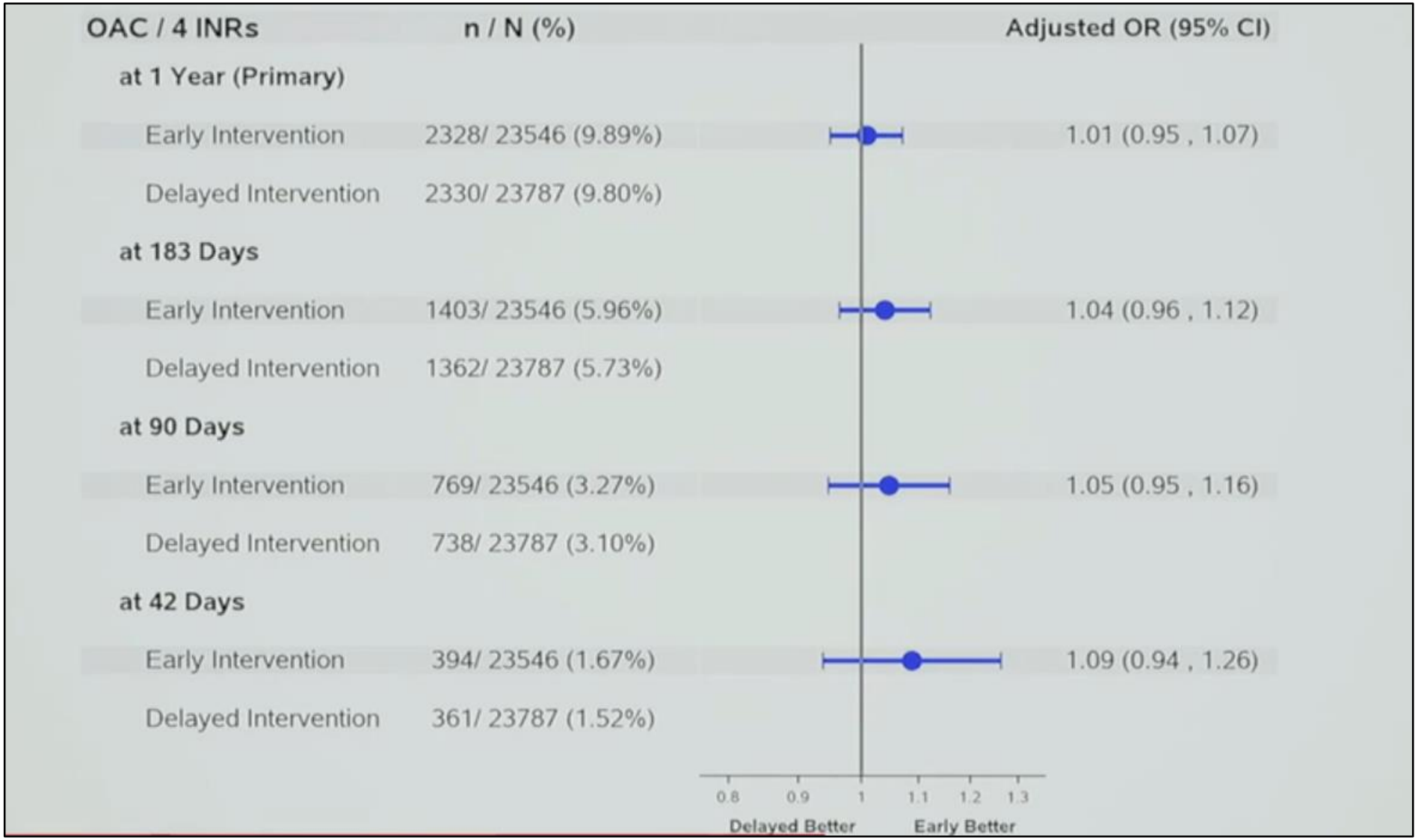
Results

- The primary endpoint of OAC initiation over the course of the 12-month trial occurred in 9.89% of patients in the intervention group and 9.80% of patients in the control group (adjusted odds ratio 1.01; 95% confidence interval 0.95–1.07).
- No statistical differences between groups regarding the secondary endpoints.

Primary endpoint



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Secondary endpoints

	Early Intervention Cumulative Incidence % (95% CI)	Delayed Intervention Cumulative Incidence % (95% CI)	Adjusted HR (95% CI)
Hospitalization for			
ischemic/ unknown stroke*	1.69% (1.51%, 1.88%)	1.74% (1.56%, 1.93%)	0.92 (0.79,1.08)
hemorrhagic stroke**	0.41% (0.32%, 0.51%)	0.34% (0.25%, 0.42%)	1.31 (0.93,1.83)
ischemic/ hemorrhagic stroke*	2.08% (1.88%, 2.28%)	2.10% (1.90%, 2.30%)	0.98 (0.85,1.13)
ischemic/ hemorrhagic stroke / systemic embolism*	2.18% (1.97%, 2.39%)	2.22% (2.01%, 2.43%)	0.99 (0.86,1.14)
any bleeding event*	1.97% (1.77%, 2.16%)	1.99% (1.79%, 2.19%)	1.00 (0.87,1.15)
ischemic/ hemorrhagic stroke/ systemic embolism/ bleeding*	3.62% (3.36%, 3.88%)	3.62% (3.36%, 3.88%)	0.97 (0.88,1.08)
All-cause in-hospital death*	2.48% (2.26%, 2.70%)	2.35% (2.14%, 2.56%)	1.03 (0.91,1.16)

**Meta-analyses were conducted using data from 2 sites.
*Meta-analyses were conducted using data from 3 sites.

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Conclusions

- Among a population with a guideline indication for OAC for stroke prevention with AF, there was no statistically significant difference in rates of OAC initiation at 1 year with a single education mailing.
- Numerically more patients initiated OAC early after mailing, raising question of whether multiple mailings or further contact may have been beneficial.
- It was feasible to identify, enroll, and obtain outcomes through this novel study design using the FDA-Catalyst Network.
- Additional trial are needed to assess feasibility of patient consent and repeat patient interactions.