

VENICE 2015 ARRHYTHMIAS

SPECIAL EDITION

FOOD & ARRHYTHMIAS



New Guidelines on Stroke Prevention for AF: Europe, Far East or USA, NICE or Not?



The NICE Guidelines

I Savelieva

St George's University of London, UK

Declaration of Interest

Task Force: Reviewer ACC/AHA/ESC Guidelines 2006, Task Force member ESC Guidelines on Atrial Fibrillation 2010, 2012, 2016, EHRA Document Writing Committee 2011 - present

PI: Bayer Pharma AG, Boehringer Ingleheim, Bristol Myers Squibb, Daiichi, Menarini, Pfizer, Sanofi, Servier, Takeda

Consultant/Advisor/Speaker: Astra Zeneka, Bayer Pharma AG, Boehringer Ingleheim, Bristol Myers Squibb, Daiichi-Sankyo, Gilead, Menarini, Mitsubishi Pharma, MSD, Pfizer, Richmond Pharmacology, Sanofi, Takeda

Value of a Clinical Guideline?

Clinical guidelines can:

- Provide **recommendations** for the treatment and care of people by health professionals
- Be used to develop **standards** to assess the clinical practice of individual health professionals
- Be used in the **education and training** of health professionals
- Help **patients** to make informed decisions
- Improve **communication** between patient and health professional

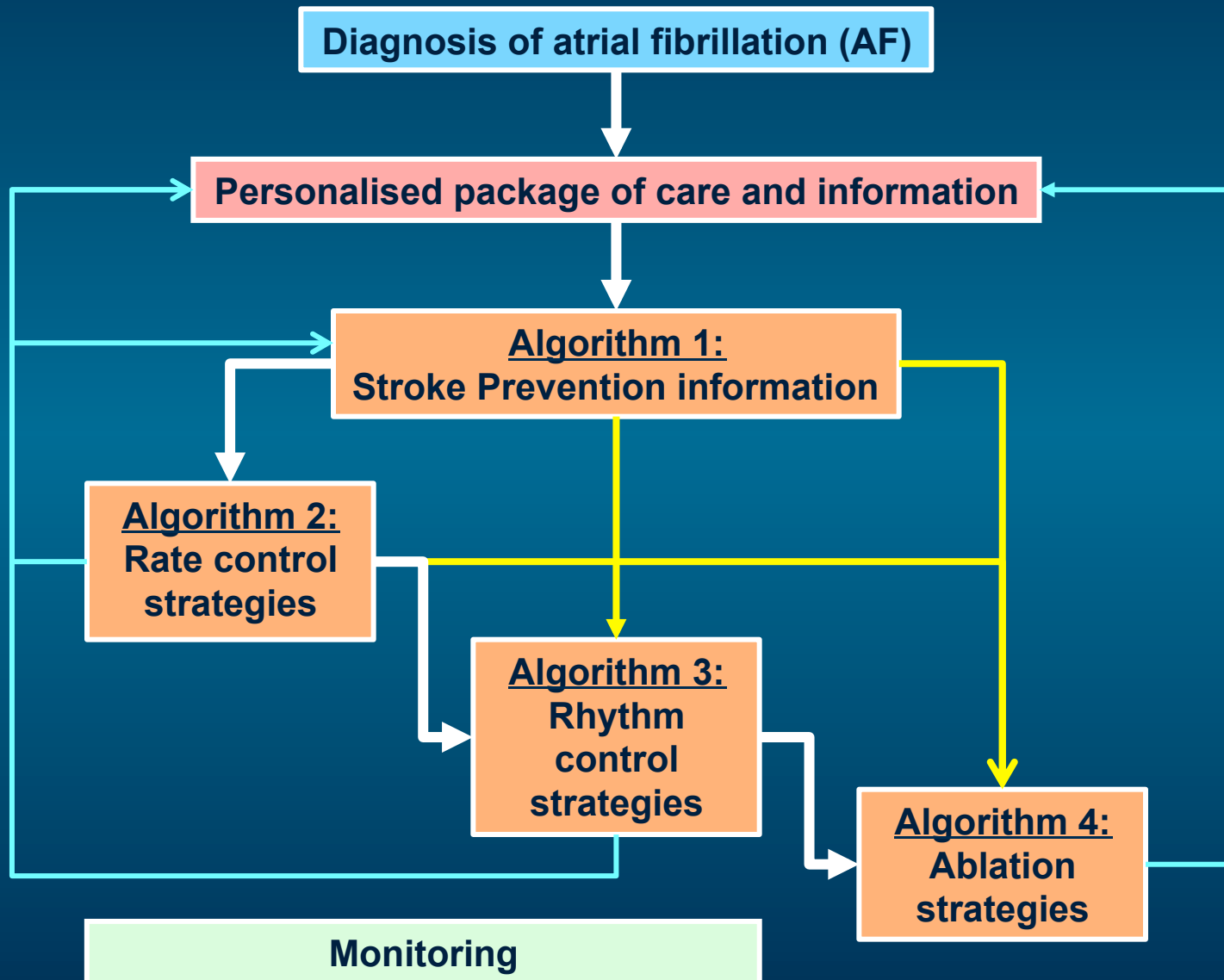
NICE 2014 AF Guidelines

Personalised Package of Care and Information

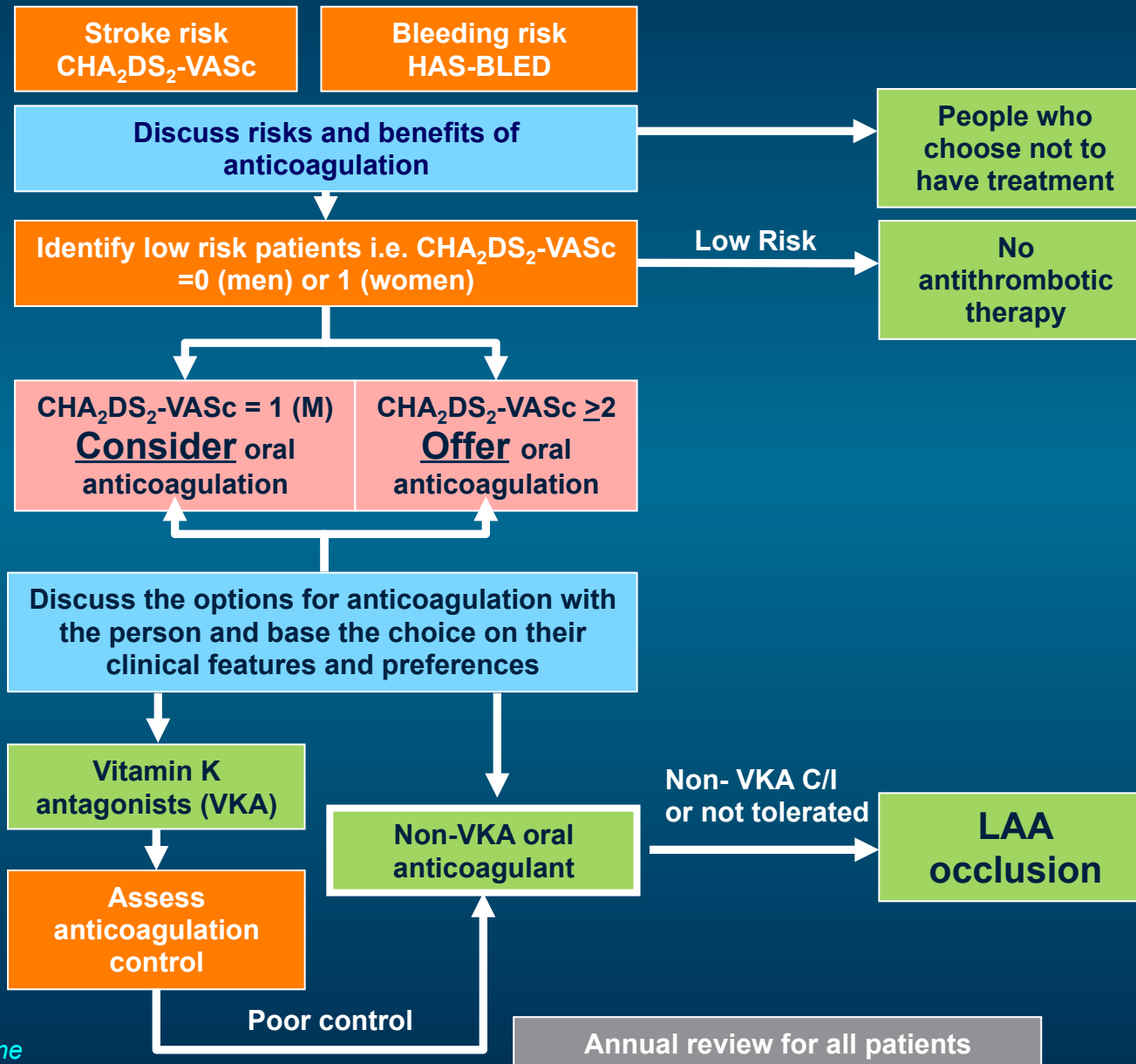
Offer people with atrial fibrillation a personalised package of care. Ensure that the package of care is documented and delivered, and that it includes:

- Stroke awareness and measures to prevent stroke
- Rate control
- Assessment of symptoms for rhythm control
- Psychological support if needed
- Up-to-date and comprehensive education and information on:
 - cause, effects and possible complications of atrial fibrillation
 - management of rate and rhythm control
 - anticoagulation
 - practical advice on anticoagulation in line with recommendations
 - support networks

NICE AF Guidelines: Care Flow

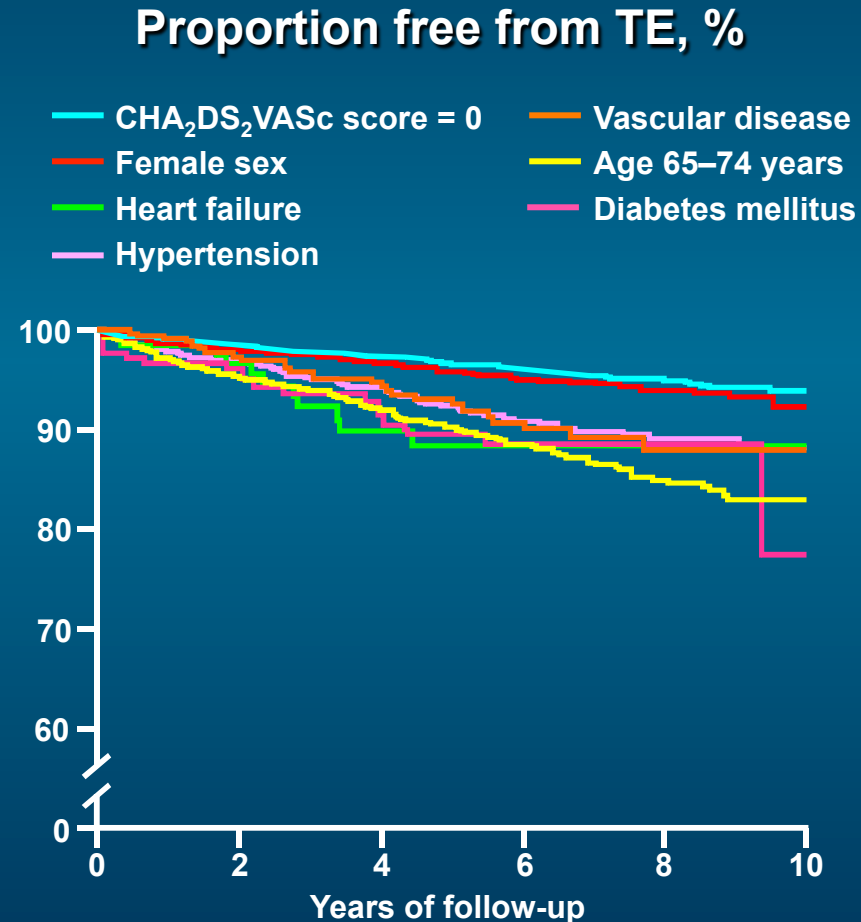


Algorithm 1. Stroke Prevention



CHA₂DS₂-VASc: Contribution of Individual Risk Factors in the Danish Cohort

Factor	Event rates, %	HR (95% CI)	p
CHF	1.78	2.69 (1.47 - 4.95)	0.001
HTN	1.49	2.26 (1.75 - 2.92)	<0.0001
DM	2.02	3.03 (1.89 - 4.86)	<0.0001
VD	1.47	2.22 (1.49 - 3.30)	< 0.0001
65-74 yrs	2.09	3.12 (2.57 - 3.78)	< 0.0001
Female	0.82	1.24 (0.98 - 1.57)	0.08



Risk of Stroke in CHA₂DS₂-VASc

Score 1: the Swedish Cohort

- Swedish nationwide health registries
- Retrospective data collection 2005-2010
- N = 140, 420
- Quarantine / blanking period after the index AF diagnosis: 4 weeks
- Follow-up: 5 years

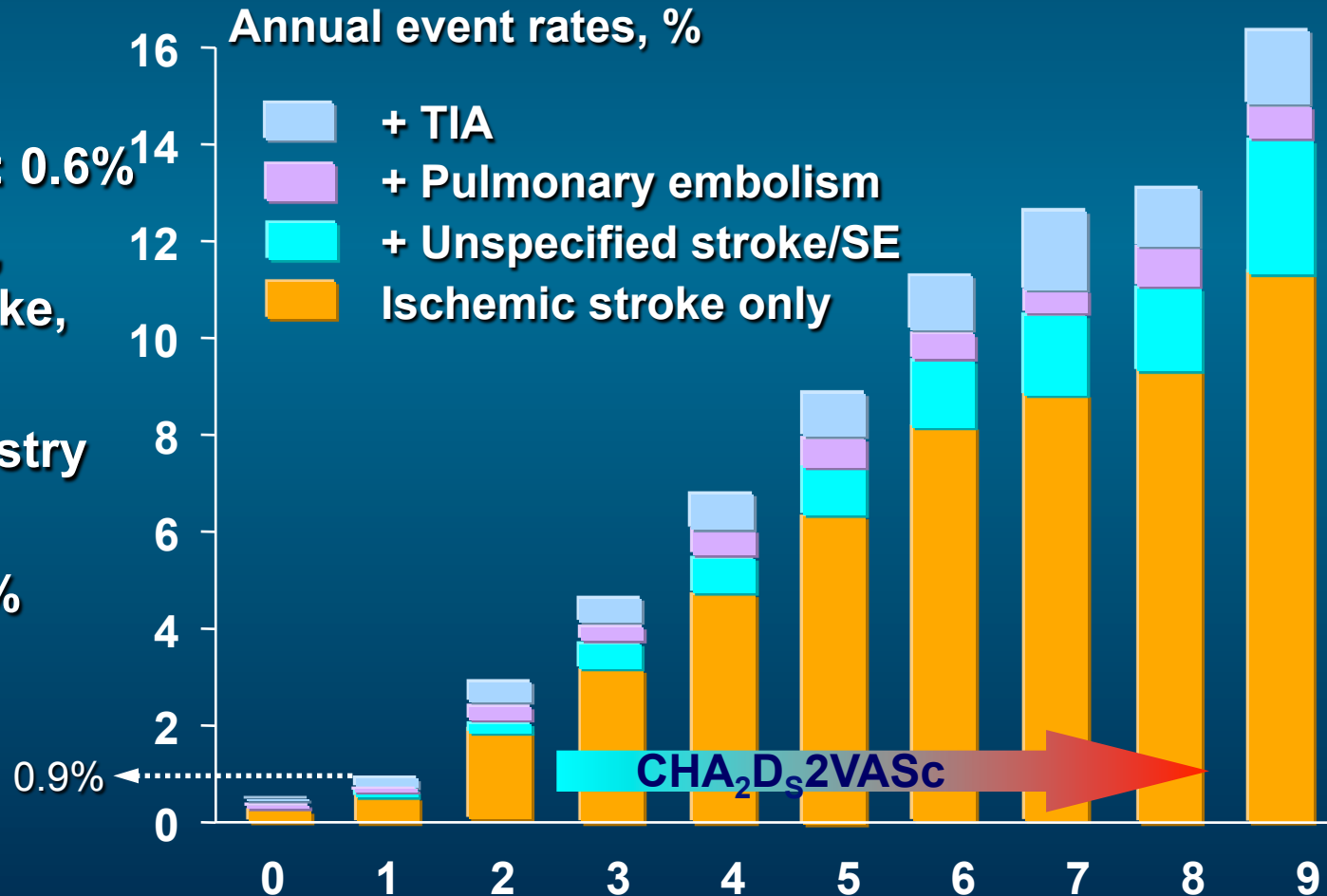
Ischemic stroke: 0.6%

Ischemic stroke, unspecified stroke, TIA, PE: 0.9%

Riks-Stroke registry only: 0.3%

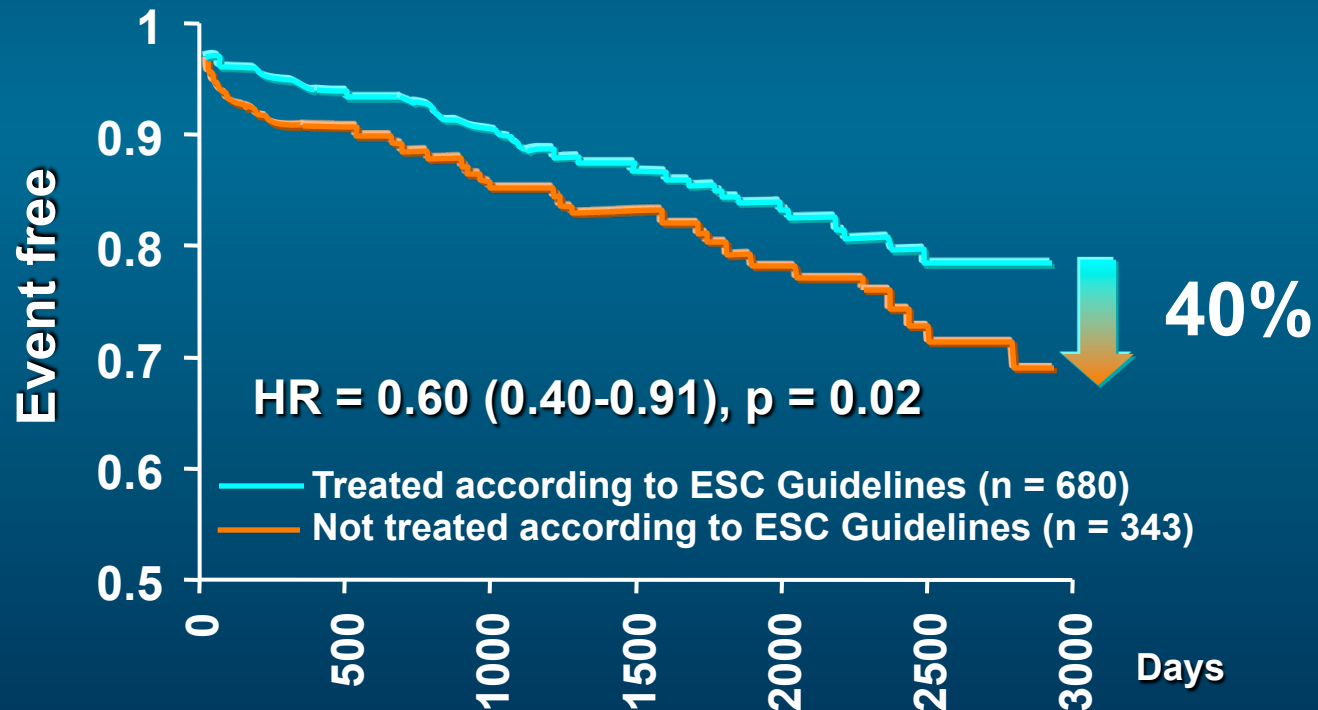
Women: 0.1-0.2%

Men 0.5-0.7%

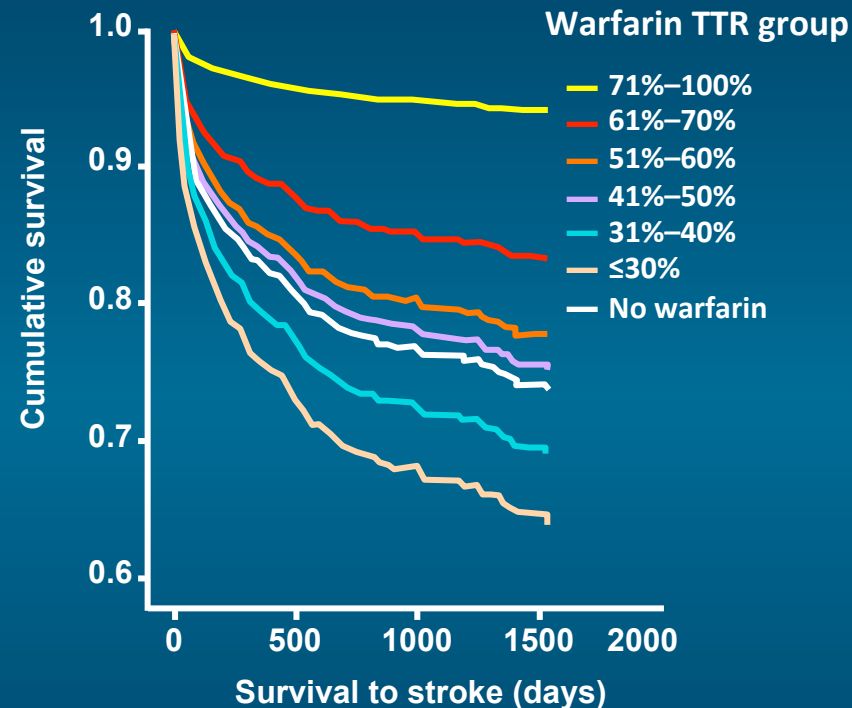
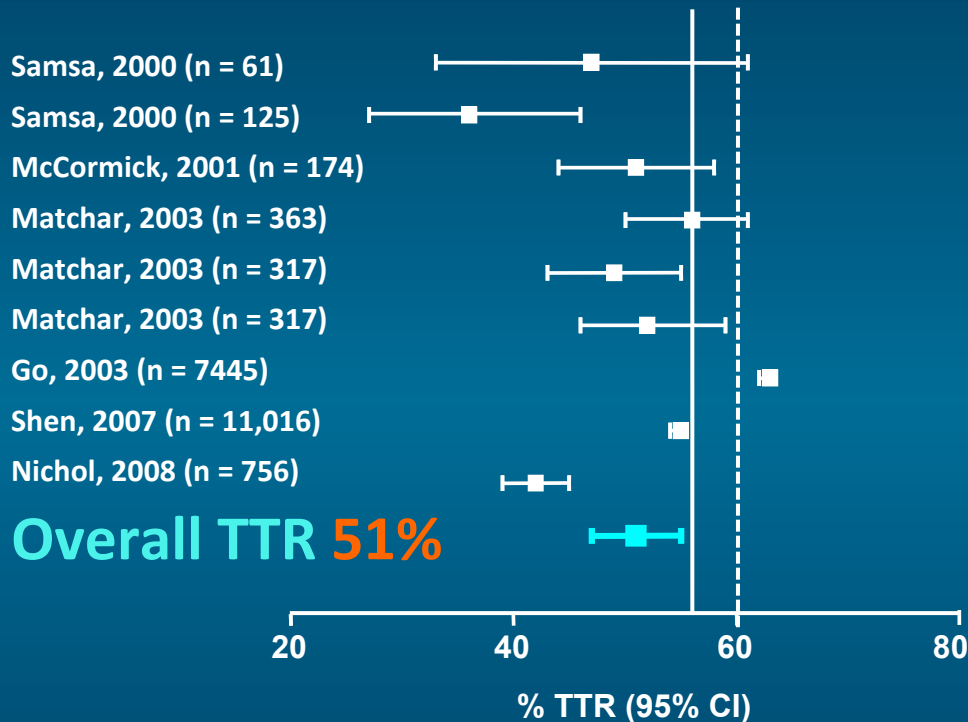


Prognosis in Patients With CHA₂DS₂-VASc 1 Treated or Not Treated According to Guidelines

- Community-based cohort study
- N = 2177 with CHA₂DS₂-VASc 1 (24% of the total population)
- 53% on OAC
- 1° EP: stroke, SE, death
- Follow-up: 2.7 years



Sub-optimal TTR and Risk of Stroke



- Meta-analysis of TTR (%) of AF patients treated with warfarin in the community
- TTR >70% is necessary to reduce **stroke** risk in patients with CHADS₂ score ≥2 compared with the non-warfarin treatment group (p=0.025)

NICE AF Guidelines 2014

Warfarin (VKA) Monitoring

Calculate the person's time in therapeutic range (TTR) at each visit
When calculating TTR:

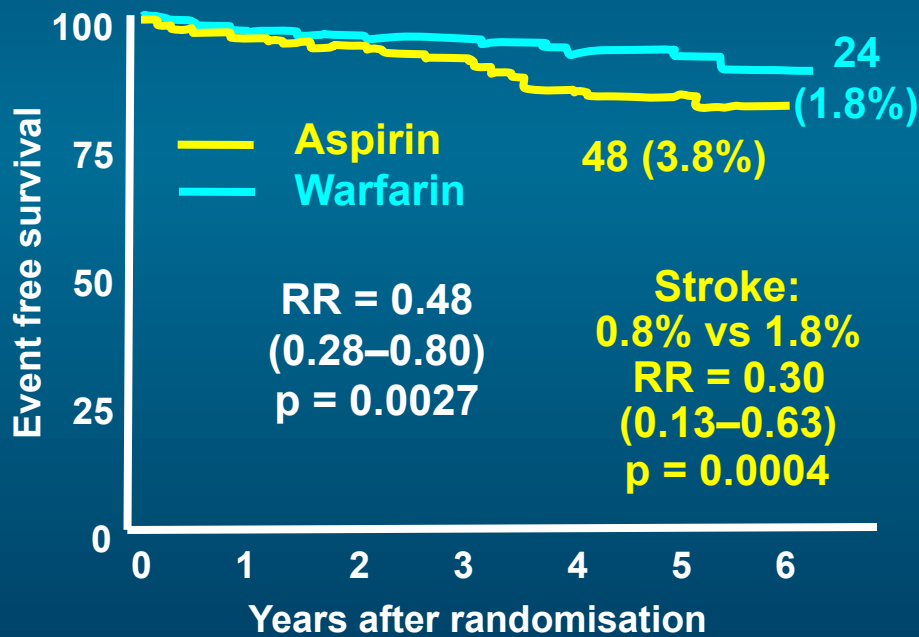
- Use a validated method such as the Rosendaal method for computer-assisted dosing or proportion of tests in range for manual dosing
- Exclude measurements taken during the first 6 weeks of treatment
- Calculate TTR over a period of at least 6 months. [new 26 2014].

Reassess anticoagulation for a person with poor anticoagulation control shown by any of the following:

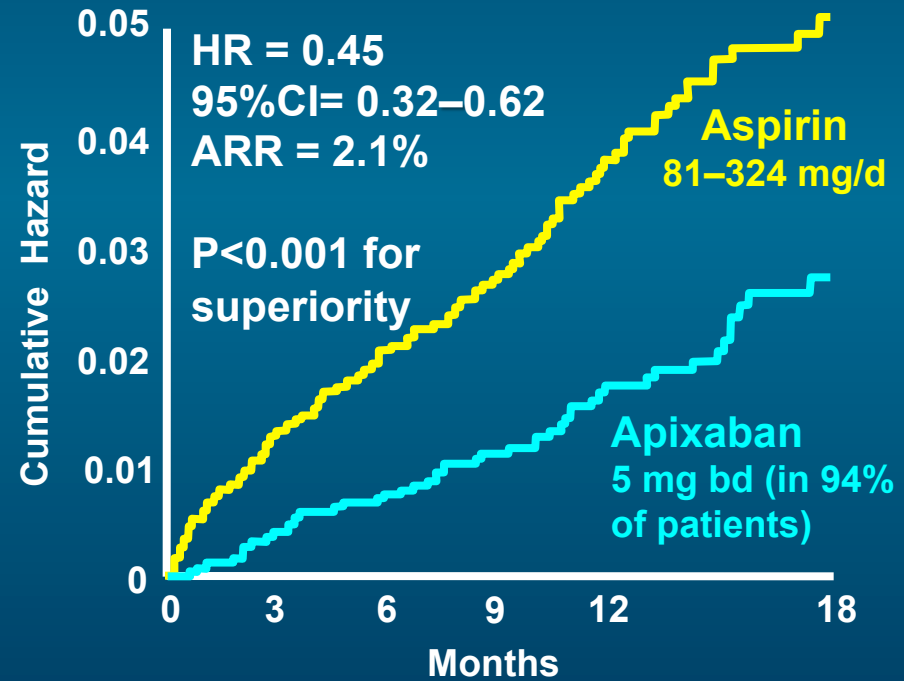
- 2 INR values higher than 5 or 1 INR value higher than 8 within the past 6 months
- 2 INR values less than 1.5 within the past 6 months
- TTR less than 65%. [new 2014]

"Efficacy" of Aspirin in BAFTA and AVERROES Trials

BAFTA: Fatal or disabling stroke, other intracranial haemorrhage or clinically significant arterial embolism



AVERROES: Stroke or systemic embolism



NICE AF 2014: Aspirin and DAPT

Do not offer aspirin monotherapy solely for stroke prevention to people with AF. [new 2014]

Only consider dual antiplatelet therapy with aspirin and clopidogrel for stroke prevention if anticoagulation is contraindicated or not tolerated and the person has a CHA₂DS₂-VASc score of 2 or above. [new 2014]

2014 NICE AF Guidelines: NOACs

The decision about whether to start treatment with **A, D or R** should be made after an informed discussion between the clinician and the person about the risks and benefits of **A, D or R** compared with warfarin. For people who are taking warfarin, the potential risks and benefits of switching to **A, D or R** should be considered in light of their level of international normalised ratio (INR) control.

[This recommendation is from for the prevention of stroke and systemic embolism in atrial fibrillation (NICE technology appraisal guidance xxx).] [20xx]

Apixaban

≥ 1 CHADS₂ RF

Dabigatran

≥ 1 CHADS₂ RF

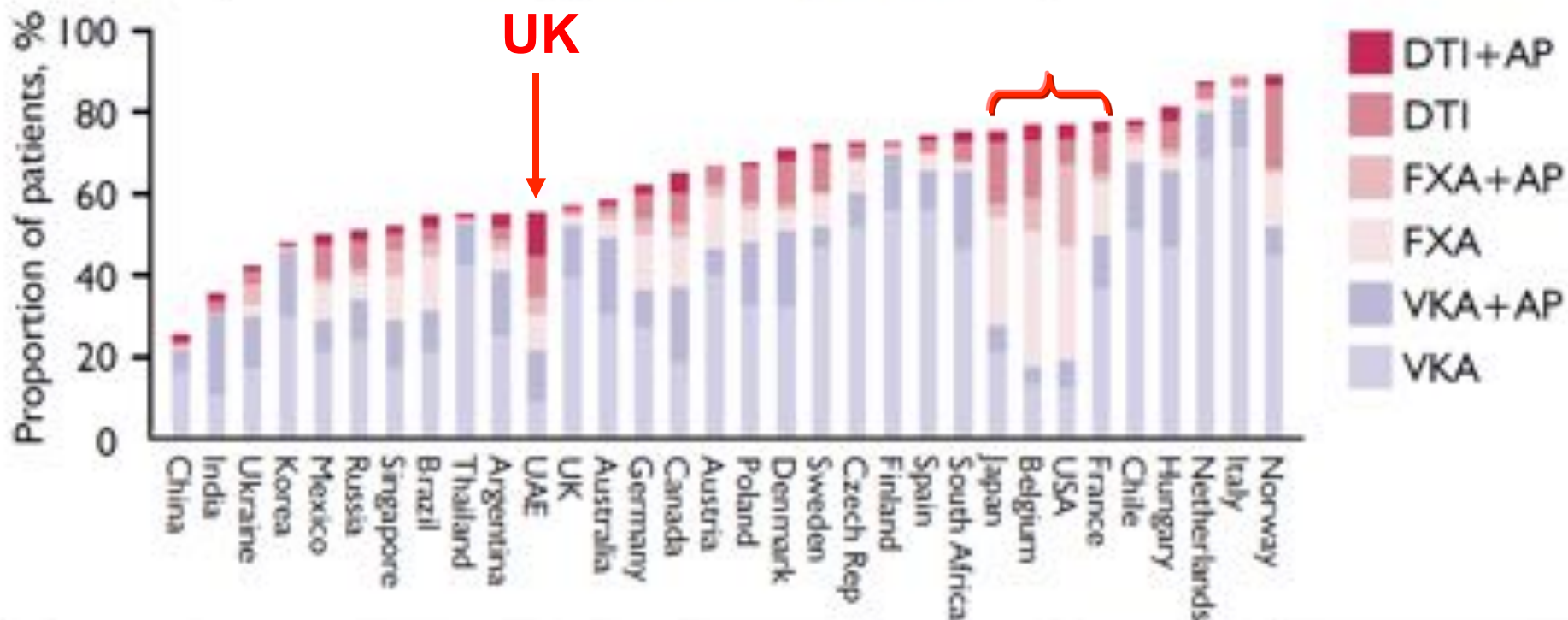
Rivaroxaban

≥ 1 CHADS₂ RF

previous stroke, TIA or SE, LVEF < 40%,
HF NYHA ≥ class 2, age ≥ 75 years, or
age ≥ 65 years with: DM, CAD or ↑BP.

GARFIELD Registry: Use of Anticoagulation and Drug Choice

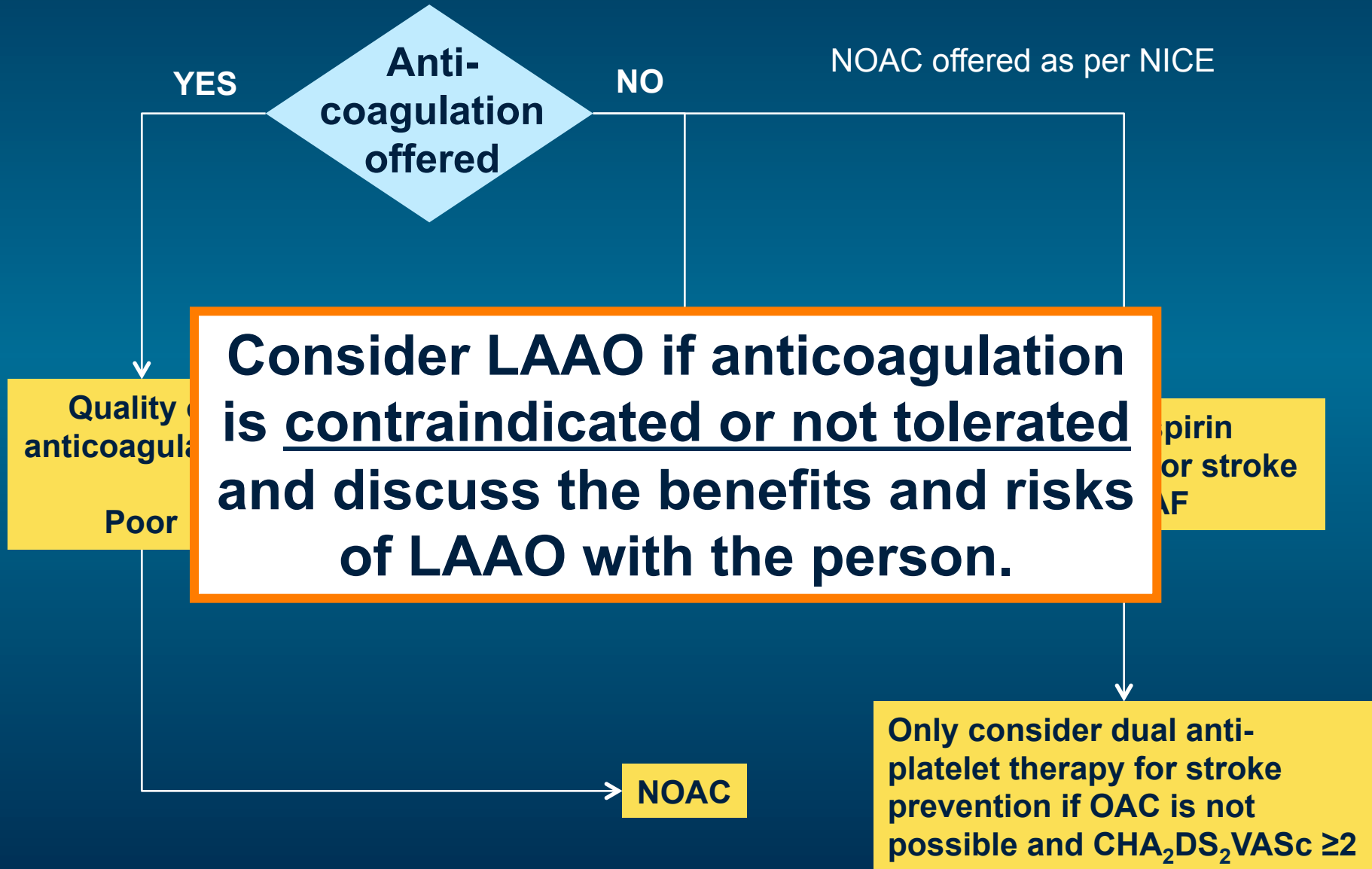
n = 17,475 enrolled in 2010-2014



NICE and Other Guidelines

Guidelines	Year	Risk stratification	OAC indicated	NOAC preferred	Role of ASA
ACCP 9 th ed.	2012	CHADS ₂	YES (≥1)	YES	CHADS ₂ = 0 if pt prefers Rx
ESC (update pending)	2012	CHA ₂ DS ₂ VASc	YES (≥1)	YES	If OAC cannot be used
APHRs (update pending)	2013	CHA ₂ DS ₂ VASc	YES (≥2)	YES (CHA ₂ DS ₂ VASc 1 but not Riva)	Not recommended, except pts with CAD/stents/TE
JCS	2014	CHADS ₂	YES (≥1)	YES (choice depends on CHADS ₂)	Not recommended
CCS update	2014	CHADS ₂	YES (≥1)	YES	CHADS ₂ = 0 + age < 65 + CAD/PAD
AHA/ACC/HRS	2014	CHA ₂ DS ₂ VASc	YES (≥2)	YES (in pts unable to take W)	CHA ₂ DS ₂ VASc = 1 (or nil, or OAC)
NICE	2014	CHA ₂ DS ₂ VASc	YES (≥2 or ≥1 in men)	NO	Not recommended

2014 NICE AF Guidelines



NICE on Anticoagulation

- Simplifies the approach to stroke prevention and promotes anticoagulation in all but lowest-risk patients
- Promotes annual review of stroke and bleeding risk
- Focuses on quality of anticoagulation control
- Removes the issue of aspirin
- Provides equality of access to VKAs and NOACs
- Provides access to LAA occlusion therapies

Algorithm 2. Rate Control Strategies

Pts with HF, AF with reversible cause or acute onset AF

Offer rhythm control irrespective of symptoms if:

- AF with reversible cause
- HF thought to be due to
- New-onset AF

Assess and offer rate control as the first-line strategy to all

Offer β -blocker or a rate limiting CCB as initial monotherapy.

Be aware of symptoms, heart rate, comorbidities and patient preferences
Consider digoxin monotherapy for non-paroxysmal AF only if sedentary
Do not offer amiodarone for rate control

Still symptomatic with monotherapy, consider combination therapy with 2 of: β -blocker, diltiazem, digoxin

If symptoms uncontrolled

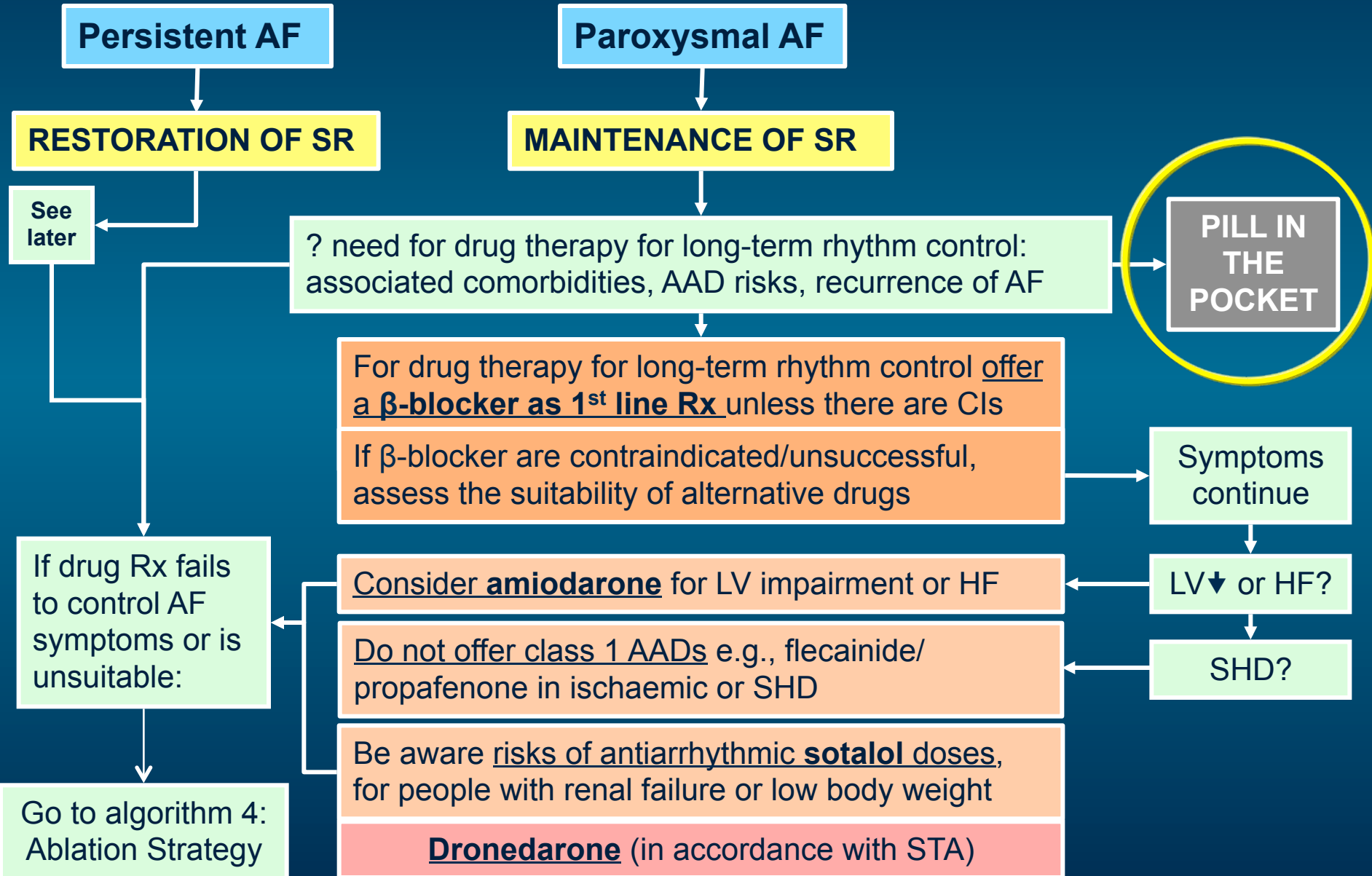
Is patient eligible for a rhythm control strategy?

Yes

Go to algorithm 3:
Rhythm Control

Go to algorithm 4:
Ablation

Algorithm 3: Rhythm Control Strategies



NICE 2014 AF Guidelines

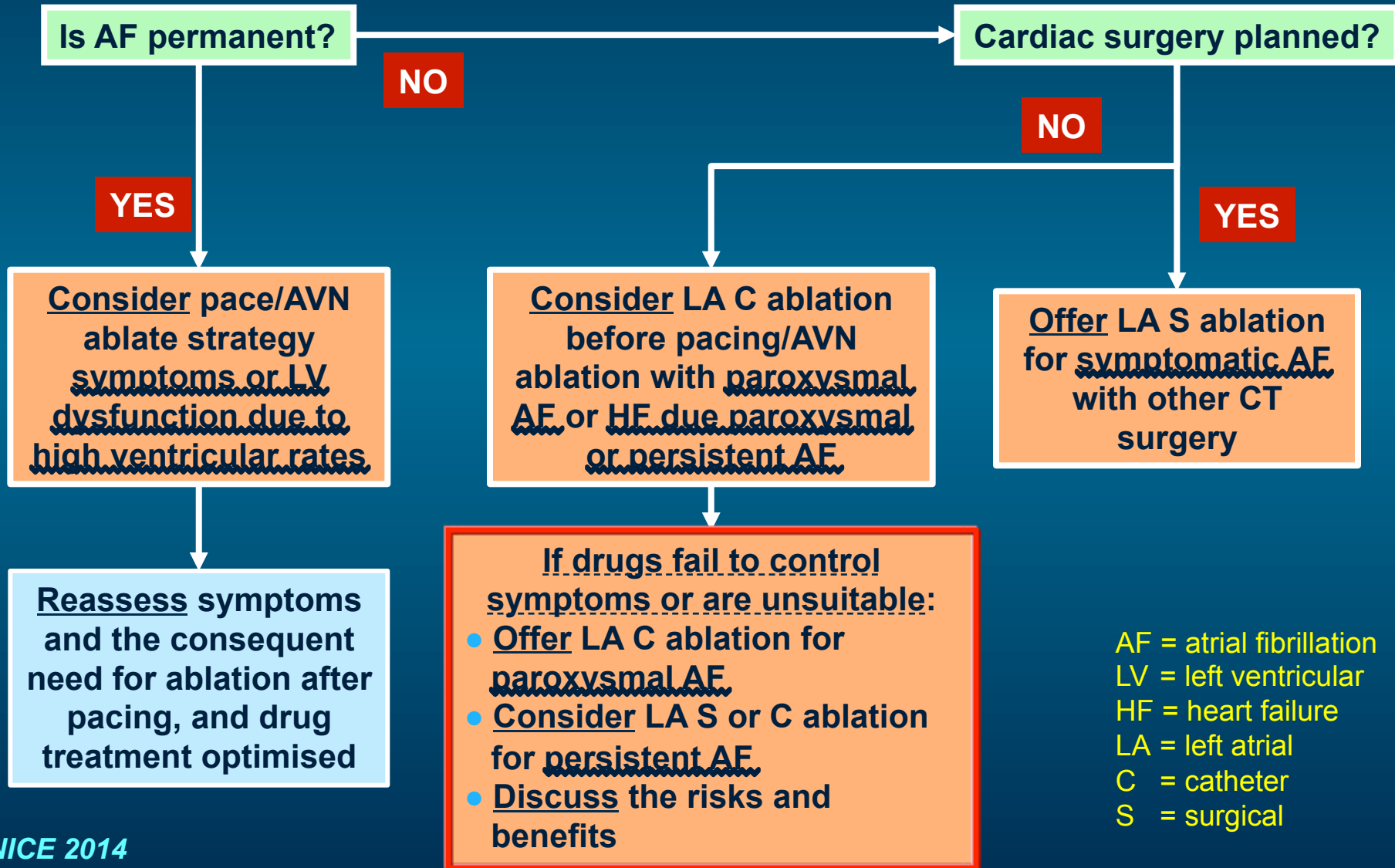
Pill-in-the-Pocket

Where people have infrequent paroxysms and few symptoms, or where symptoms are induced by known precipitants (such as alcohol, caffeine), a 'no drug treatment' strategy or a 'pill-in-the-pocket' strategy should be considered and discussed with the patient.

In people with paroxysmal atrial fibrillation, a 'pill-in-the-pocket' strategy should be considered for those who:

- have no history of left ventricular dysfunction, or valvular or ischaemic heart disease and
- have a history of infrequent symptomatic episodes of paroxysmal atrial fibrillation; and
- have a systolic blood pressure greater than 100 mmHg and a resting heart rate above 70 bpm and
- are able to understand how to, and when to, take the medication.

Algorithm 4: Left Atrial Ablation



Conclusions

- NICE Guidelines offer a structured, patient-centered approach to management of AF
- NICE Guidelines follow the ESC recommendations on stroke risk stratification and prevention, including LAAO devices
- NICE Guidelines adopt rate control as first-line therapy in patients who are asymptomatic
- NICE Guidelines consider rhythm control an appropriate strategy for symptomatic patients
- NICE Guidelines regard left atrial ablation a valuable therapy, but exercise a more conservative approach to using it as first-line therapy

Thank you!



St George's
University of London