All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

All Wales Risk/Benefit Assessment Tool for Oral Anticoagulant Treatment in People with Atrial Fibrillation

October 2013

This report has been prepared by a multiprofessional collaborative group, with support from the All Wales Prescribing Advisory Group (AWPAG) and the All Wales Therapeutics and Toxicology Centre (AWTTC), and has subsequently been endorsed by the All Wales Medicines Strategy Group (AWMSG).

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PURPOSE

Following the publication of All Wales advice on the role of oral anticoagulants, it became apparent that there was a need in NHS Wales for an All Wales risk/benefit assessment for oral anticoagulant treatment in people with atrial fibrillation (AF).

The tool supports a consistent approach for people with AF, both in hospital and GP settings, to promote:

- an assessment of stroke risk,
- an assessment of bleeding risk,
- effective annual assessment, and
- data collection/audit trail.

ALL WALES RISK/BENEFIT ASSESSMENT TOOL FOR ORAL ANTICOAGULATION TREATMENT IN PEOPLE WITH AF

To be completed and documented prior to initiating treatment with oral anticoagulant and as an annual review for patients taking oral anticoagulants.

Patient addressograph	Consultant: Directorate: Date:	Logo/practice

Refer to the All Wales Advice on the Role of Oral Anticoagulants[1].

The focus of AF management should be to identify affected people and undertake stroke risk assessment using the $CHADS_2$, or the more recently introduced CHA_2DS_2-VASc, risk assessment tool.

Assessment of bleeding risk should be carried out using an appropriate tool, such as HAS-BLED.

CHADS2 scoring system (stroke risk stratification scheme)

Risk factor		Points	Score
None		0	
C	Heart failure	1	
H	Hypertension	1	
A	Age ≥ 75	1	
D	Diabetes mellitus	1	
S_2	Stroke/transient ischaemic attack	2	
		Total	

CHA_2DS_2-VASc scoring system (alternative stroke risk stratification scheme)

Risk factor		Points	Score
None		0	
C	Heart failure/left ventricular dysfunction	1	
H	Hypertension	1	
A_2	Age ≥ 75	2	
D	Diabetes mellitus	1	
S_2	Stroke/transient ischaemic attack/thromboembolism	2	
V	Vascular disease	1	
A	Age 65–74	1	
Sc	Female	1	
		Total	

For people with a $CHADS_2$ score ≥ 2, chronic oral anticoagulation (OAC) therapy is recommended, unless contraindicated.

People with a $CHADS_2$ score < 2 require further assessment, and the CHA_2DS_2-VASc risk assessment tool can aid the decision.

HAS-BLED scoring system (risk assessment for bleeding in AF patients on anticoagulation)[2]

Letter	HAS-BLED bleeding score: Clinical characteristics	Points	Score
H	Hypertension defined as systolic blood pressure > 160 mmHg	1	
A	Abnormal renal function (chronic dialysis, renal transplantation or serum creatinine ≥ 200 micromoles/l)	1	
	Abnormal liver function (chronic hepatic disease e.g. cirrhosis, or biochemical evidence of significant hepatic derangement e.g. bilirubin more than twice upper limit of normal in association with aspartate aminotransferase/alanine aminotransferase/alkaline phosphate more than three time upper limit normal etc.)	1	
S	Previous history of stroke, especially deep brain stroke	1	
B	Previous history of bleeding, anaemia or predisposition to bleeding	1	
L	Unstable INRs or poor time (< 60%) in therapeutic range	1	
E	Elderly – Is the patient ≥ 65 years?	1	
D	Drugs predisposing to bleeding such as antiplatelets and non-steroidal anti-inflammatory drugs (NSAIDs)	1	
	Is there evidence of alcohol excess?	1	
		Total*	

Use of the HAS-BLED score should be used to identify modifiable bleeding risks that need to be addressed, but should not be used on its own to exclude patients from OAC therapy[3].

The HAS-BLED score per se should not be used to exclude patients from OAC therapy, but allows clinicians to make an informed assessment of bleeding risk (rather than relying on guesswork) and, importantly, makes them think of the correctable risk factors for bleeding, e.g. uncontrolled blood pressure, concomitant use of aspirin/NSAIDs, labile INRs, etc.

Other clinical/social factors to be considered†

Other clinical and social factors for consideration	Yes	No	Action/Date
Does the patient have a registered GP?			
Is the patient being investigated for or receiving treatment for cancer? Active venous thromboembolism + cancer: low molecular weight heparin not warfarin AF + cancer: given the heterogeneous nature of patients with cancer, the risks and benefits for continued anticoagulation should be assessed individually and reviewed periodically[4,5].			
Is the patient taking over the counter medications or frequent antibiotics?			
Is there evidence of trips or falls?			
Does the patient have any sensory, visual or literacy deficits without carer support?			
Is there any evidence of Alzheimer's or possible problems with mental capacity?			
Is the patient of child bearing age?			

Review this form at least annually, in addition to:

1. Compliance (check time in therapeutic INR range if on warfarin)
2. Thromboembolic events
3. Bleeding events
4. Other side effects
5. Co-medications and over the counter drugs
6. Check renal function: impaired renal function may constitute a contraindication or recommendation not to use the anticoagulant medicine, or may require a dose reduction; recommendations differ for warfarin, dabigatran, apixaban and rivaroxaban.

*NB: In patients with a HAS-BLED score ≥ 3, caution and regular review are appropriate[3]

HAS-BLED Score	n	Bleeds, n	Bleeds/100 patients*
0	798	9	1.13
1	1286	13	1.02
2	744	14	1.88
3	187	7	3.74
4	46	4	8.70
5	8	1	12.50
*p for trend of increasing bleeding risk with increasing score = 0.007			

† Adapted from risk/benefit tool produced by Haematology Department, Royal Gwent Hospital.

Patient addressograph	Clinician: Directorate: Date:	Logo/practice

INITIAL ASSESSMENT	
$CHADS_2$ score	
If $CHADS_2$ score < 2, CHA_2DS_2-VASc score	
Risk assessment completed?	
HAS-BLED score NB In patients with a HAS-BLED score ≥ 3, caution and regular review are appropriate	
Other clinical/social factors checked?	

CHOICE OF AGENT
Refer to the All Wales Advice on the Role of Oral Anticoagulants if considering an **oral anticoagulant, noting warfarin first line‡ for most people will support the managed entry of the newer agents.**

Agent	Please tick	Rationale for decision and dose prescribed
No anticoagulant or thromboprophylaxis given		
Warfarin INR 2–3		
Apixaban (Eliquis®▼)		
Rivaroxaban (Xarelto®▼)		
Dabigatran (Pradaxa®)		
Other (please state)		

‡ Use of the term “first line” relates to the preferred treatment option, but does not preclude the use of other agents where appropriate. AWMSG advice does not affect the clinical freedom of the prescriber.

INDICATION	Please tick all that apply
Warfarin has been prescribed for prophylaxis of systemic embolism in patients with rheumatic heart disease and AF.	
Dabigatran has been prescribed for the prevention of stroke and systemic embolism in adults with non-valvular AF with one or more risk factors, such as:	
Previous stroke, transient ischaemic attack or systemic embolism	
Left ventricular ejection fraction < 40%	
Symptomatic heart failure, NYHA ≥ Class 2	
Age ≥ 75 years	
Age ≥ 65 years **associated with one of the following:**	
Diabetes mellitus	
Coronary artery disease	
Hypertension	
Rivaroxaban has been prescribed for the prevention of stroke and systemic embolism in people with non-valvular AF with one or more risk factors, such as:	
Congestive heart failure	
Hypertension	
Age ≥ 75 years	
Diabetes mellitus	
Prior stroke or transient ischaemic attack	
Apixaban has been prescribed for the prevention of stroke and systemic embolism in adults patients with non-valvular AF with one or more risk factors, such as:	
Prior stroke or transient ischaemic attack	
Age ≥ 75 years	
Hypertension	
Diabetes mellitus	
Symptomatic heart failure (NYHA Class ≥ II)	
CONTRAINDICATIONS[§]	**Please tick all that apply**
A lesion or condition, if considered a significant risk factor for major bleeding. This may include:	
current or recent gastrointestinal ulceration	
presence of malignant neoplasm at high risk of bleeding	
recent brain or spinal injury	
recent brain, spinal, or ophthalmic surgery	
recent intracranial haemorrhage	
known or suspected oesophageal varices	
arteriovenous malformation	
vascular aneurysms, or major intraspinal or intracerebral vascular abnormalities	
Concomitant treatment with any other anticoagulant agent	

[§] The contraindications, posology, and warnings and precautions for use specific to each medicine, together with the individual's risk factors for bleeding (e.g. renal function), should be considered before prescribing these medicines[6]. There is no specific antidote available for apixaban, dabigatran or rivaroxaban. Please consult the product information for advice on treatment in the event of bleeding complications, or overdose. A full list of contraindications, warnings and information on posology can be found in the individual Summaries of Product Characteristics for apixaban, dabigatran, rivaroxaban and warfarin[7–10].

PATIENT DISCUSSION	Please tick
Patient understands risks and benefits of antithrombotic medication	
Patient understands and agrees with decision to prescribe antithrombotic medication	
Written information provided:	

Prescriber name (print)	
Signature	
Bleep no/ext	
Authorising consultant	
Date	

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