



Waitemata
District Health Board
Te Wai Awhina

Dabigatran and Atrial Fibrillation

From 1st July 2011, dabigatran is funded for use in patients with non-valvular atrial fibrillation and CHA_2DS_2 VASc ≥ 2 . The RE-LY¹ trial showed that dabigatran had superior efficacy compared with warfarin for reducing stroke risk at a dose of 150mg BD, and a comparable efficacy at 110mg BD. The risk of major bleeding was similar at the higher dose, with a lower risk of bleeding at the 110mg BD dose.

Two important points regarding this drug have led us to advise caution when first prescribing this drug to your patients.

- 1) **This drug is renally excreted**
- 2) **The effect of this drug is not reversible**

The following is advised

1. **Always check baseline creatinine clearance (calculated, using Cockcroft & Gault);** do not rely on eGFR as supplied by laboratory
 - Dabigatran is contraindicated for those with CrCl < 30 ml/min
 - Caution for patients with CrCl 30-50 ml/min and/or ≥ 80 yrs: if considered, use 110mg BD dose and monitor renal function regularly e.g. 3 monthly; discontinue if CrCl < 30 ml/min
 - Check CrCl if significant intercurrent illness especially where patient is likely to become dehydrated e.g. gastroenteritis
 - In all patients, regular monitoring of renal function e.g. every 3-6 months is advisable
2. **Reassess eligibility:** Recheck CHA_2DS_2 VASc (risk of stroke) and HAS-BLED (risk of bleeding) scores (overleaf) prior to changing from warfarin to dabigatran. If HAS-BLED ≤ 3 , use 150mg BD; if > 3 use 110mg BD. To compare % stroke risk with % bleeding risk, see <http://www.mdcalc.com/has-bleed-score-for-major-bleeding-risk>
3. **Caution with concurrent anti-platelet use due to increased risk of bleeding, as for warfarin**
4. **Dabigatran is not suitable for patients with high bleeding risk; there is no effective reversal strategy**
5. **If bleeding:** discontinue drug, check renal function, TT, APTT and discuss with haematologist/cardiologist
6. **If unsure, do not change from warfarin without seeking specialist advice**
 - Our experience with dabigatran is limited; avoid changing large numbers of patients from warfarin to dabigatran until more experience is gained.
 - Make sure the INR is less than 2 before changing from warfarin to dabigatran
 - In elderly patients, at risk of falls/bleeding, the consequences may be worse with a non-reversible anticoagulant
 - Problems with reversal are expected to be greatest in those patients who bleed with supra-therapeutic drug levels i.e. those dosed inappropriately for their renal clearance

Important: This is a general guide provided to assist clinicians with the use of dabigatran. Users of this guide must always consider current best practice and use their clinical judgement with each patient. This guide is not a substitute for individual clinical decision making.

HAS-BLED bleeding risk score		
Letter	Clinical characteristic *	Points awarded
H	Hypertension	1
A	Abnormal renal and liver function (1 point each)	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile INRs	1
E	Elderly (e.g. age > 65 years)	1
D	Drugs or alcohol (1 point each)	1 or 2
		Maximum 9 points

*Hypertension: systolic blood pressure > 160 mmHg

Abnormal renal function: chronic dialysis or renal transplantation or serum creatinine \geq 200 μ mol/L

Abnormal liver function: chronic hepatic disease (e.g. cirrhosis) or biochemical evidence of significant hepatic derangement (e.g. bilirubin > 2x upper limit of normal with AST/ALT/ALP > 3x upper limit normal etc)

Stroke: previous stroke

Bleeding: previous bleeding history and/or predisposition to bleeding, e.g. bleeding diathesis, anaemia etc

Labile INRs: unstable/high INRs or poor time in therapeutic range (e.g. < 60%)

Drugs or alcohol: concomitant antiplatelet agents, NSAIDs, or alcohol abuse etc

CHA ₂ DS ₂ -VASc stroke assessment tool	
Risk factor	Score
Congestive heart failure/LV dysfunction	1
Hypertension	1
Age \geq 75	2
Diabetes mellitus	1
Stroke/TIA/thromboembolism	2
Vascular disease*	1
Age 65-74	1
Sex category (i.e. female sex)	1
Maximum score	9

*Prior MI, peripheral artery disease, aortic plaque

Adjusted stroke rate according to CHA ₂ DS ₂ -VASc score		
CHA ₂ DS ₂ -VASc score	Patients (n=7329)	Adjust stroke rate (%/year)
0	1	0%
1	442	1.3%
2	1230	2.2%
3	1730	3.2%
4	1718	4.0%
5	1159	6.7%
6	679	9.8%
7	294	9.6%
8	82	6.7%
9	14	15.2%

Tables adapted from: The Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC) Guidelines for the management of Atrial Fibrillation European Heart Journal 2010;31:2369–2429

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