New Guidance for use of Dabigatran, Apixaban and Rivaroxaban for patients with AF undergoing DC Cardioversion

### Introduction

Dabigatran, apixaban and rivaroxaban (the so called novel oral anticoagulants or NOACs) are all NICE approved licensed alternatives to warfarin for stroke prevention in patients with non-valvular Atrial Fibrillation (AF). Patients with severe renal impairment (eGFR <30ml/min) should avoid NOACs and continue to be prescribed oral anticoagulation with warfarin. Currently, it is the policy that all patients on a NOAC require a transoesophageal echocardiogram (TOE) to exclude left atrial appendage thrombus, prior to undergoing an elective DCCV at SDH.

However, all 3 of the NOACs have data to support their use as safe and non-inferior alternatives to warfarin in the trial setting without the need for a TOE. 1,2,3 In addition, dabigatran is included in the most recent updated ESC guidelines as an alternative to warfarin in patients undergoing cardioversion. 4

Dabigatran has also been show to improve the efficiency of an elective DCCV service as there is no need for weekly warfarin testing and both delays and cancellations secondary to sub-therapeutic INRs will be significantly reduced.5

### **Prior to Cardioversion**

Patients are to be initiated on one of the NOACs for 3 weeks before an elective DC cardioversion and will remain on the drug for a further minimum of 4 weeks post procedure (as per updated ESC guidelines).5  If patients are to remain anticoagulated after this point they may either remain on the selected NOAC, switch to an alternative NOAC or else be switched to warfarin if they do not have a licensed indication for a NOAC (ie they have significant valve disease).

### **Prior to Cardioversion**

The choice of NOAC will be at the discretion of the Consultant in charge although as dabigatran is the only NOAC included in current guidelines it should be considered first line .

* Patients identified for DCCV will be referred to Ros Morris to book a date for their DCCV.
* Patients should be also be referred to the anticoagulation clinic where they will receive counselling and information of potential side effects and what to do if these occur will be explained to patients. that they may be switched to warfarin if they are to remain on anticoagulation longer term. Patients will be given a card stating which anticoagulant they will be taking.
* Patients must have up to date U&E’s, LFT’s, baseline clotting and recent TFT’s. If they do not then the patient should be sent for the appropriate blood tests at the initial clinic visit to check these.
* The patient’s drug history will be checked prior to initiation of a NOAC by the clinician listing for DCCV to check for any significant interactions and to confirm suitability. Importance of drug compliance will be strongly emphasised.
* Patients should be issued an SDH prescription for 28 days supply so that it is known both that the patient has the drug and when it was started
* The patient will subsequently be contacted to arrange the date of the procedure and will be asked about any side effects.
* **At the pre-admission visit**, **2-3 days before DCCV**:
* It will be checked that they have had both a CXR and an echocardiogram and the results confirmed
* A repeat 12 lead ECG to confirm AF
* A repeat U&E’s should be checked and either an aPTT or PT depending on type of NOAC (see below)
* The patient will be given a BHF patient information booklet.

**Pre-admission visit**

* + There are currently no gold standard measurements for any of the NOACs, however,

dabigatran does prolong activated partial thromboplastin time aPTT and both apixaban and rivaroxaban prolong prothrombin time (PT). Measurements of these indirectly infers patient compliance.

* Therefore patients taking dabigatran should also have an aPTT measured whilst patients taking either apixaban or rivaroxaban should have a PT measured.
* Patients will be asked to confirm and sign a consent form that includes declaring that they are compliant with their anticoagulant medication whilst accepting the risk of an embolism if not (*Appendix 1 – Updated DCCV Consent form including Patient Compliance Statment*)
* On the day of the cardioversion patient compliance will once again be verbally confirmed prior to proceeding.
* **If the patient has missed 2 or more consecutive doses in the preceding week of the procedure then the procedure should be deferred for a minimum of a further week.**
* **Patients should have their DCCV deferred where the coagulation screen is normal (ie normal aPTT or PT) suggesting that the patient is not compliant and therefore not anti-coagulated**

### **Post Cardioversion**

* Following the procedure the patient will continue on the NOAC for a minimum of 4 weeks and followed up as detailed by the Consultant at the time of listing for the procedure.
* Prior to this appointment a routine ECG should be performed
* If sinus rhythm has been maintained then the decision whether to continue or stop anticoagulation can be discussed with the patient.
* If the patient is in atrial fibrillation then further treatment options can be discussed as appropriate

### **Prescribing Information**

* The dose of dabigatran is 150mg twice daily if aged under 80 years old (see below if abnormal renal function). Patients either aged over 80 years or with moderate renal impairment (eGFR 30-50 mls/min) should be given 110mg twice daily.
* The dose of apixaban is 5 mg twice daily or 2.5mg twice daily if moderate renal impairment
* The dose of rivaroxaban is 20 mg once daily or 15mg daily daily if moderate renal impairment
* All 3 are contra-indicated in severe renal impairment (eGFR < 30ml/min)
* Switching of warfarin to a NOAC; stop warfarin and start NOAC once INR < 2

### **References**

1. Connolly SJ, Ezekowitz M, Yusuf S et al. Dabigatran versus Warfarin in patients with Atrial Fibrillation. *N Engl J Med* 2009;361:2673-2674
2. Granger CB, Alexander JH, McMurray JJ et al. Apixaban versus Warfarin in patients with Atrial Fibrillation. *N Engl J Med* 2011;365:981-992
3. Patel MR, Mahaffey KW, Garg J et al. Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation. *N Engl J Med* 2011;365:883-891
4. Camm AJ, Lip G, De Caterinea R et al. 2012 focused update of the ESC Guidelines for the management of atrial fibrillation. *Eur Heart J* 2012;33,:2719–2747
5. Choo WK, Fraser S, Padfield G et al. Dabigatran improves the efficiency of an elective direct current cardioversion service. *Br J Cardiol* 2014;21:29-32

Appendix 1

Patients Declaration of Compliance to Therapy

### Why is this required?

In patients with atrial fibrillation the irregular heart rhythm can lead to the formation of small blood clots in the upper chambers of the heart, these may then become dislodged and travel through the bloodstream.

These clots may then come to rest anywhere in the body, however if they lodge within the small vessels in the brain they can be one cause of what is commonly referred to as a stroke

…………… is an anticoagulant drug which slows blood clotting with the purpose of preventing these blood clots from forming. However due to its short duration of action if patients miss a dose (or doses) they may temporarily lose the anticoagulant effect, which in turn may allow the formation of small clots before the effect of the drug is restored after the next dose taken.

As the action of electrical cardioversion is such that any existing clots might inadvertently be forced into the circulation, it is therefore vitally important that the anticoagulant drug is taken regularly without a break for the three weeks prior to the procedure (and in particular the week before cardioversion) to ensure no clots are present at the time of the procedure.

### Declaration

I, Mr/Mrs/Ms …………………………. declare that I have taken the ……………. as directed on the label for the three weeks prior to today without a break i.e. with no missed doses.

I understand that if this is not the case then I may be at increased risk of adverse effects following cardioversion, in particular cerebrovascular events (stroke).

Signed

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Document Control Information

### Consultation Schedule

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| --- | --- |
| Name and Title of Individual  | Date Consulted |
| Anthony Jones, Consultant Cardiologist | 01/05/2014 |
| Manas Sinha, Consultant Cardiologist | 01/05/2014 |
| Susie Lewis, Consultant Cardiologist | 01/05/2014 |
| Ros Morris, Staff Nurse in charge of DC cardioversion, Cardiology | 01/05/2014 |
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The following people have submitted responses to the consultation process:

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| --- | --- |
| Name and Title of Individual  | Date Responded |
| Anthony Jones, Consultant Cardiologist | 06/05/2014 |
| Manas Sinha, Consultant Cardiologist | 07/05/2014 |
| Susie Lewis, Consultant Cardiologist | 08/05/2014 |
| Ros Morris, Staff Nurse in charge of DC cardioversion, Cardiology | 01/05/2014 |
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