

NICE to review new oral anticoagulant Dr Matthew Fay discusses Dabigatran

Dr Matthew Fay helps to explain Dabigatran.

Atrial fibrillation (AF) is the commonest sustained heart rhythm problem, affecting over 1% of the population and is more common the older we become, with a staggering one in ten people over eighty suffering from AF.

While for some, AF causes symptoms ranging from breathlessness and palpitations to fatigue, for others, AF may appear to have no symptoms at all. However, what is very important is that AF for all increases the risk of stroke by up to five fold, and if combined with other illness and in an older person, it can raise the individual's annual risk of stroke to almost 20%.

“For many years, Warfarin has been the only drug option”

Long term, proven scientific data has established that thinning the blood with Warfarin can reduce the risk of stroke in AF by a staggering 70%; and if you were to suffer a stroke while taking Warfarin, the stroke can be less severe than would have been expected in an individual with AF not taking Warfarin.

For many years, Warfarin has been the only drug option to offer this level of protection from stroke. However, in 2011 it is expected that the first of several new drugs will become available. Dabigatran (Pradaxa) is expected to be licensed in the late Autumn to reduce the risk of stroke in AF.

The way a blood clot forms is very complex and involves multiple steps. While Warfarin affects several stages where enzymes rely on Vitamin K, and



Dr Matthew Fay, GPwSI

this leads to a final process where a compound called fibrinogen is converted into fibrin (the stuff of clots), Dabigatran only affects this final step.

Drugs that change the clotting process are called ‘anticoagulants’ or ‘blood thinners’. The final part of the clotting process involves an enzyme called thrombin; this converts fibrinogen to fibrin (the stuff of clots). For this reason Dabigatran is called a Direct Thrombin Inhibitor – ‘Direct’ because it affects the enzyme directly, not through the Vitamin K enzymes like Warfarin. ‘Thrombin’ as this is the enzyme affected. ‘Inhibitor’ as it prevents the enzyme action and reduces the amount of fibrin around to form clots.

In the RE-LY medical study (involving more than 18,000 AF patients), Dabigatran was shown to be as good as Warfarin. In people where their Warfarin is not easily controlled, so have a lot of high or low INR readings, Dabigatran was shown to be better than Warfarin. In those people where the Warfarin INR readings were stable and in range most of the time Dabigatran was as good as Warfarin.

Unlike Warfarin that can be affected by what we eat, how well we are or what medications we may be asked to take, Dabigatran is not. This means that it does not require monitoring in the same way as Warfarin. Although there are technical

tests available to assess how effective Dabigatran is these, are not routine and should not be routinely performed.

However, Dabigatran does not have an antidote, if there is a severe bleeding problem then the doctors have to replace blood loss, if it is possible, until the effects of Dabigatran stop. Other blood thinners (anticoagulants) do have antidotes.

Although Dabigatran is already in use in the UK, this is for other indications (conditions, not for AF). Dabigatran will have to obtain a license for use to prevent strokes in AF. The first part of this process was completed in April 2011 and it is expected that it will proceed to obtain a UK license in June 2011. After this date the production company will have to produce the UK stock to supply pharmacies.

Since Dabigatran does not require close monitoring (unlike Warfarin), any doctor can prescribe it. However, as with any new medications, initially this may be a Consultant in a hospital or General Practitioners who have a special interest in this area or who are specifically trained for Dabigatran.

“Dabigatran does not require close monitoring”

As to who will be able to receive it, this will ultimately be decided by the National Institute of Health and Clinical Excellence (NICE) who will review the evidence and cost effectiveness of Dabigatran and then make recommendations.

People who are unable to take Warfarin or the other alternatives but are at risk of stroke due to AF will likely be considered for Dabigatran, and probably people who are unable to regulate their INR, may also be considered.

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At its current price Dabigatran is at least three times more expensive than Warfarin even without the need to monitor it (Warfarin as a medication is extremely cheap), so it is likely to have some restrictions on its use given the current cost pressures on the NHS.

In conclusion, Dabigatran is clearly a great step forward for people with Atrial Fibrillation who are at risk of stroke. There has not been an alternative for Warfarin for many years. Clearly Warfarin remains the first line choice with its great wealth of evidence of effectiveness and the extensive experience of use. However for those who cannot take Warfarin, Dabigatran is a very effective medication that is likely to be as safe to use as Warfarin and as effective at reducing strokes in AF.

Harry had endured symptomatic AF for many years

Drug therapy had initially helped, but when Harry found himself in long-term persistent AF his doctors agreed that he was a suitable candidate for ablation to relieve symptoms.

A clinical decision to improve his quality of life. This is his story...



My Atrial Fibrillation was discovered when investigating a supposed neurological condition in 2000. It was accompanied by Tachycardia, Bradycardia and 1st degree heart block and was at first paroxysmal (intermittent) then became 24/7 by early 2006. Because I tolerated the AF reasonably well and my heart rate was controlled, I hadn't noticed the change.

Cardiologists continued to conduct tests and monitor developments. I had also seen two electrophysiologists (EPs) by this time, both of them believing, on balance of risk vs. symptoms, that it was too early for a PVI ablation. Because of my slow heart rate at night, I resisted the anti-arrhythmic drug Flecainide, which the first EP recommended in 2004. The second discharged me back to my GP in 2006 with Bisoprolol and Clopidogrel to wait and see developments.

Symptoms worsened

Within a year it often felt like a bag of fighting monkeys in my lower left chest and other symptoms worsened. I also now felt cut off from specialist care, so after more tests arranged by my GP I asked for a referral back to a cardiologist in 2008. His objective was to keep heart rate in normal range - Bisoprolol dosage increased yet again. At my request I was referred to my third EP - diagnosis was now persistent long standing AF with a slow ventricular response, meaning heart rate was still well controlled.

New outlook for long-term persistent AF

Times and techniques change. My new EP was prepared to undertake a PVI ablation, explaining that it would probably require two, maybe three ablations to achieve a long-term symptom free condition - this was the target rather than an actual 'cure'. He was and still is of the firm opinion that long-term persistent AF is not permanent AF until such time as the normal heart rhythm cannot be restored. So, it's as much a candidate for a PVI ablation as PAF and recent onset persistent AF. At no time were budgetary factors mentioned; it seemed to be purely a clinical decision as he was confident that my quality of life could be improved.

The route to PVI ablation

Not totally straightforward. First was Warfarin and three months of Amiodarone before an internal cardioversion in July 2009, to see if normal heart rhythm felt better than the AF alternative. It did until it crashed out within days. Then occasional flashes of pain in chest caused a delay - were they cardiac? An angiogram revealed CAD (70% occlusion of one vessel) but heart MRI determined pains were not ischemic (cardiac).

So, after more than four years of AF 24/7, the first ablation was in March 2010 but I slipped back into AF within four weeks. For the second ablation

in June 2010 he used the Hansen Robotic system that provides greater precision and supported it with three months post-procedure Amiodarone therapy. Now in early 2011 I remain in normal rhythm and mostly symptom free - I feel so much better than before that I wish I hadn't prevaricated about having it done.

Lessons learnt

I have been fortunate - I found both ablations remarkably pain free and for the six hours involved each time I was mostly asleep, in a haze of pleasant sedation. Furthermore, all this was done on the NHS. My GP was highly supportive, the first EP was a PVI ablation pioneer, the second a foremost expert in AF ablations and the third is a rising light in a leading centre in UK and has great experience and interest in ablating long-standing persistent AF.

However, I've also helped myself. Firstly I ignored my AF whenever possible and worked around it, whilst making sure I received adequate treatment and care. To do this it's necessary to research and understand AF so you can speak to medical professionals with confidence - most now seem to respond positively to this approach and engage with you in achieving the best outcome possible. List questions in advance and make notes at all appointments. Above all, both parties should put it in writing, so any actions proposed are clear and understood. Finally, be kind to your consultant's secretary, she can often prove to be your best friend.

AFA Patient Day, Sunday 2nd October 2011

Birmingham Hilton Metropole Hotel

Reserve your place now, places are going fast!

This year's agenda offers topical discussion, up to date news, insight into emerging therapies and opportunity to hear from a faculty boasting world leading arrhythmia specialists.



Representatives from the Department of Health, NHS Improvement, Primary Care, arrhythmia nurses, electrophysiologists and cardiothoracic surgeons, make up the impressive Faculty this year at the Heart Rhythm Congress.

An 'early bird' rate of £20.00 is available until June 30th, but only to members booking directly with AFA. Please email or complete the slip below to reserve your place.

Regular updates and further information is available on:
www.afa.org.uk

AGENDA

- 10:30 Assessing the Risks**
What are they? A focus on stroke prevention, anticoagulation and emerging treatment options (including devices)
- 11:00 What other drugs might I be given?**
Assessing other risks and symptoms from anti-arrhythmic drugs/ beta blockers and their side effects
- 11:30 Other treatment options for AF**
When is catheter ablation an option and who is suitable for this procedure? Pace and ablate: the risks and the benefits
- 12:15 Questions to the panel**
- 12:30 Lunch**
- 13:45 AF and You**
What exercise should I do? Can I work, drive and travel? What support services are available? The AFA Forum
- 14:25 The changing NHS – debate and discussion, in the new NHS where will AF be managed?**
Role of GP commissioning boards, secondary and tertiary centres
- 15:30 Update from AFA**

View full details on www.afa.org.uk

Book directly with AFA to receive 50% discount.

The following early bird rates apply:
£20.00 until 30th June 2011
£25.00 until 31st August 2011
£30.00 until 1st October 2011
£50.00 on the day



Registration Form

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Please tick the box whether you are: **Patient**

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If you are a UK tax payer please tick to allow AFA to claim an extra 28p for every £1.00 you donate, at no extra cost

Please post completed registration form with cheque, made payable to AFA to:

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'Putting Pulse into Practice'

Heart Rhythm Week: 6th – 12th June 2011

Your countdown to the big week begins!

This year's Heart Rhythm Week (formerly known as Arrhythmia Awareness Week) will be the **biggest this country has ever seen...**

Awareness, education, parliamentary and fundraising activities will take place across the length and breadth of the country, to highlight the need for routine pulse checks when someone visits their GP surgery.

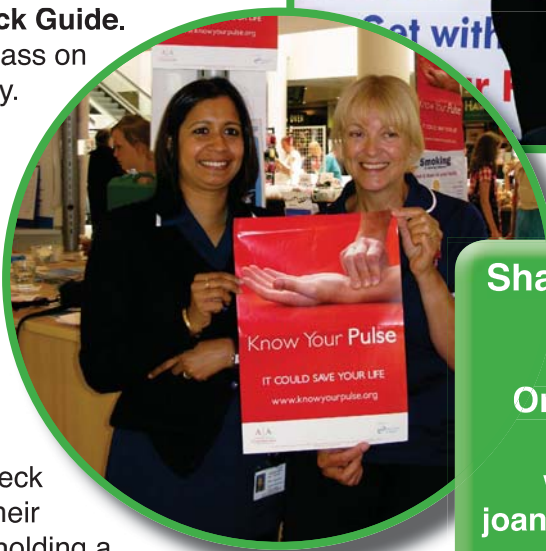
**Join us in 'Putting Pulse into Practice'...
'Know Your Pulse'**

Take your pulse with the **Pulse Check Guide**. Order your Pulse Check Guides to pass on to your friends, colleagues and family.

'Put Pulse into Practice'

Order a **'Posters and Leaflets Pack'** for your local GP surgery, hospital, medical centre, care home, local school, work place, and community centre.

Order a **'Pulse Check Pack'** – This pack is for those holding a Pulse Check Clinic teaching people how to take their pulse. It can also be used for those holding a display stand at your local hospital, shopping centre, GP surgery or community centre.



Share your plans, events and ideas with us!

Order your Awareness Week packs now:
www.heartrhythmweek.org
joanna@heartrhythmcharity.org.uk
+44 (0)1789 451 823

Fundraising News



Raffle Winners

1st Prize - £100

**R Day
Bedlington**

2nd Prize - £75

**H Watson
Isle of Man**

3rd Prize - £50

**J Robinson
Droylsden**

Thank you to all those who continue to support AFA, we are indebted to your generosity. In the past few months David Turner raised over £2000 through events held at his local golf club; while Andrea Bates joined the Hastings Half Marathon, Victoria Wilson participated in the Brighton Half Marathon and winter Olympian Debbie Palmer-Green completed the Finland Ice Marathon. Total sponsorship for these marathons netted in excess of £1300!

AFA is currently recruiting for the 2012 London Marathon. If you feel up for a challenge, please contact: jo@afa.org.uk for details.

Easy ways you help AFA

- A tax payer? Please consider signing the AFA gift aid form and allow us to claim an extra 28p for every £1.00 you donate!
- Use e-bay? Link to AFA and every purchase will also benefit AFA!
- Consider donating through standing order
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For further details on any Fundraising initiative contact wendy@afa.org.uk