Atrial Fibrillation Association

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Providing information, support and access to established and new treatments for atrial fibrillation

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Request by Atrial Fibrillation Association for Guidance on Dabigatran etexilate for the prevention of stroke and systemic embolism in Atrial Fibrillation

AFA is mindful that budgetary pressures within heath care services are ever-present and inevitable, and as a result, cost effectiveness has to be a reasonable expectation before new therapies can be recommended. However when comparing treatments it is important not to just consider cost but also effectiveness and this should take into account the wide gap between clinical trial data and real clinical practice. While this difference has been recognised for some time AFA firmly believes that: **'value must also be measured by outputs, not inputs. Hence it is patient health results that matter,'**

The AFA has amassed and documented the experiences of a vast number of patients and health care workers that have been shared with us. These accounts are a true representation of the "health results" of patients suffering from AF in today. In light of this amassed patient feedback and respected published data we have formulated the following summary of point on behalf of patients suffering from AF:

1) **AF is the greatest risk factor for stroke and results in more severe strokes**

2) **Patients with AF are not prescribed appropriate stroke prevention in the vast majority of cases**

3) **The main reasons for this are patient and physician resistance to using warfarin.**

4) **For those patients on warfarin large numbers of patients are difficult to control and spend >60% outside the target therapeutic range – rendering warfarin of no benefit.**

5) **Dose adjusted, well managed warfarin remains the first choice therap however, warfarin alone is unable to prevent expensive strokes. An alternative has now become available and should be considered for those patients unable to maintain INR**

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We present arguments for these points in more detail as follows.

1) **AF is the greatest risk factor for stroke**

Atrial Fibrillation is known to be responsible for 45% of all embolic strokes, resulting in more many preventable strokes per year. AF strokes are usually more severe and cause more death and disability. Research indicates that 80,000 AF patients assessed at high risk of stroke, are not receiving anticoagulation, and 70% of current stroke patients known to have AF are not prescribed an anticoagulant. Embolic strokes are likely to be more debilitating and more expensive than other strokes. While post-discharge costs need to include costs associated with long term disability or the human cost. The well-documented and persistent failure of warfarin adequately to reduce stroke risk results in thousands of preventable ischemic strokes attributable to AF. The AFA suggests that these preventable strokes should be factored into end costs.

2) **Patients are not prescribed appropriate stroke prevention**

In clinical trials warfarin has been associated with a stroke risk reduction in AF patients of 50%-70%. However, this potential is not being realised in routine clinical practice, leaving thousands at risk of preventable strokes. Warfarin is under-prescribed for many reasons including the complexity of dosing and patient management as well as fear of the associated bleeding risks. Consequently, almost half the AF patients for whom warfarin is indicated are not on warfarin and remain at extremely high risk of severe, debilitating and expensive strokes.

3) **The main reason for lack of stroke prevention is patient and physician resistance to using warfarin**

Management of warfarin is complex and time-consuming for primary care physicians who currently gain equal financial reward for prescribing aspirin to tackle stroke prevention in AF patients. There is therefore great incentive against prescribing warfarin. It is also recognised that those at greatest risk, the elderly, are less likely to be given warfarin because of perceived fear of complications. However although the ERG had been tasked to consider QAL for AF patients 75+, there are large numbers of younger patients who should also be prescribed anticoagulants including 'those with a history of stroke and those aged 65 years or over with one of the following: diabetes, coronary artery disease, or hypertension.' The AFA has collected survey evidence from this age. Of those still in employment, 54% reported that warfarin had a very high impact on their job and employment. This will be increasingly relevant as the age of the population and retirement ages increase.

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4) **For those patients on warfarin large numbers of patients are difficult to control and spend >60% outside the target therapeutic range – rendering warfarin of no benefit.**

As few as 18% of AF patients are adequately treated to prevent stroke. Estimates vary but only 60-70% of AF patients are thought to be diagnosed. Of those, 97% are considered at moderate or high risk, and hence in need of anticoagulation therapy according to the most recent international expert consensus guidelines. Published evidence on the amount of time patients spend in therapeutic range indicate that of warfarinised AF patients, only 56% are within range at any one time.

As simple combination of these numbers suggests that at any one time, warfarin is effectively and safely reducing stroke risk in only 18-21% of AF patients.

5) **AFA agrees the use of warfarin as the first choice therapy. However AFA calls for the approval of a safe alternative in order to reduce preventable strokes, resulting in terrible suffering and a high financial burden – to the individual, their family and the state.**

AFA strongly believes that comparison of dabigatran with well-controlled warfarin is ignoring the cost of stroke those patients in whom warfarin is ineffective or impossible to use. A fair comparison is therefore to aspirin or to nothing. We would propose that dabigatran should be recommended for the following patients if they are at moderate or high risk of stroke according to the $CHADS_2VASc_2$ system:

a) those in whom warfarin is poorly controlled (<70% time in therapeutic range) or in whom complications result from poor control (bleed/TIA/stroke)
b) those for whom warfarin INR monitoring will limit their opportunity to access work, maintain employment and access promotion

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Conclusions:

AFA calls for guidance on dabigatran to be issued with consideration to the points AFA has highlighted in its response to the appraisal consultation document.

Jo Jerrome
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