Arrhythmia Alliance – Response NICE Appraisal Consultation Document for Rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation

It is estimated that the UK diagnoses just 60 -70% of AF patients, of those, 97% are believed to be of moderate to high risk of stroke and based on the most recent international professional consensus guidelines, should be anti-coagulated. The NICE review of literature in 2006 showed that only 54% of these patients were actually prescribed warfarin. Looking at these figures, it suggests that the risk of stroke is only reduced in 18%-21% of patients with AF.

45% of all embolic strokes are caused by AF; the stroke is usually more severe resulting in more death and disability. In the first year following a stroke, the medical outlay is £9,500 - £14,000 with embolic strokes being the most costly.

Clinical trials show that Warfarin can potentially reduce stroke risk by 50% - 70-%, however in routine clinical practice, this potential is not being achieved, risking the possibility of thousands of preventable strokes. There are many reasons for the under prescription of warfarin ranging from fear of associated bleeding risk to the complexity of dosing and patient management. At the moment, almost 50% of patients with AF for whom warfarin is suitable for, are not prescribed warfarin and so remain at risk of a stroke with devastating consequences.

Patient and physician resistance to using warfarin is a major factor in the lack of stroke prevention. Warfarin is a time consuming and complex drug for primary care practitioners and the elderly, those at most risk of stroke, are the most likely not to be prescribed warfarin due perceived fear of complications.

Data collected from younger AF patients who, according to NICE guidelines should be prescribed anti-coagulants, 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' reveals that 54% of those prescribed warfarin state that it has impacted on their job and employment enormously, suggesting the need for an alternative to warfarin.

For those who are prescribed warfarin, there are large numbers of people that are difficult to keep within therapeutic range and can spend more that 60% out of therapeutic range and so causing warfarin to be of no benefit.

NICE's 2006 review of literature concluded that of the patients indicated, just 54% of patients actually receive warfarin and of those, just 56% are within therapeutic range at any one time. These numbers would suggest that just 18% - 21% of AF patients on warfarin are effectively and safely protected from the risk of stroke.

Cost effectiveness must of course be considered, but when comparing an alternative then effectiveness must also be taken into account including the wide gap between clinical trial data and real clinical practice.

Arrhythmia Alliance believes that the comparison of Rivaroxaban with well controlled warfarin ignores the cost of stroke in those patients for whom warfarin is ineffective or impossible to use.

It would be reasonable then to compare Rivaroxaban to aspirin or to nothing. It would therefore suggest that denial of a new, safe and more effective treatment for these patients is not based on a fair comparison.

A-A would advocate that use of Rivaroxaban for the following patients, based on their risk of stroke using the $CHADS_2$/$CHADS_2VASc_2$ system:

- Those patients for whom INR monitoring will limit their opportunity to access work, maintain employment and access promotion

- Those patients for whom warfarin is poorly controlled, that spend less than 70% in therapeutic range or in whom complications such as bleed, TIA or stroke result from poor control.

Conclusion

The prime concern of the NHS is to reduce the number of strokes and so A-A does not consider that the current recommendations are reliable or that they represent an appropriate basis for guidance to the NHS. These recommendations act against the priority of the NHS to lower the number of strokes, despite trial evidence and expert witness statements. Arrhythmia Alliance believes that this will result in –

- A continued rise in the number of strokes due to Atrial Fibrillation

- Discord between patients and clinicians

- No local guidelines, leading to inequality of services, care and cost efficiencies

- Promotion of unwarranted inequalities in stroke risk reduction

A-A therefore asks the Committee to issue guidance on Rivaroxaban, taking into consideration the points raised in the response to the appraisal document.

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