

PACELINE INC



Review of Anticoagulation Therapies in Atrial Fibrillation

Submission of Paceline Incorporated
Association

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Paceline Incorporated Association's written submission to the review panel for the Review of Anticoagulation Therapies In Atrial Fibrillation.

Executive Summary

In accordance with the Terms of Reference, this submission does not consider all aspects under review, but rather those that directly impact upon the treatment options open to atrial fibrillation patients.

Whilst the terms of reference appear to cover all aspects of current and potential treatment through anticoagulation therapy, the theme of many of the reference terms appears to be how current treatments, namely warfarin, can be better used. Whilst this is an important component of the review, it is of concern to Paceline INC and those it supports as cost benefits seem to be taking precedence over maximising patient care and outcomes through the introduction of new treatments.

Introduction

Paceline INC is pleased to provide the following submission to be considered as part of the Review of anticoagulation therapies in atrial fibrillation.

About Paceline INC

Paceline Incorporated Association is a not for profit entity created to promote the objectives outlined below:

- Raise awareness of cardiac arrhythmias (including atrial fibrillation)
 - The root causes
 - The social and family issues
 - The health care issues
 - Diagnostic & prognostic paths
 - Treatment options
- Raise much needed funds to increase understanding of the causes of arrhythmias and to produce life changing treatments or cures
- Work with partner organisations in order to achieve the above-mentioned objectives.

Atrial Fibrillation Overview

- Atrial fibrillation is a major cause of stroke in Australia. These strokes are generally more severe and more likely to be life threatening than other types of strokes
- People with Atrial Fibrillation are up to seven times more likely to have a stroke than the general population
- People with Atrial Fibrillation are up to three times more likely to experience heart failure
- The cost to the Australian economy of Atrial Fibrillation alone is around \$1.25 billion every year¹
- The condition is responsible for more than 45,000 hospitalisations each year
- Atrial fibrillation is an insidious condition that has a significant impact on the health, life expectancy and quality of life of thousands of Australians.

¹ Stroke Foundation, The Economic Costs of Atrial Fibrillation in Australia, 2010.

Issues Considered in this Submission

Current options for improving the health outcomes of patients with atrial fibrillation treated with anticoagulants.

For many decades atrial fibrillation patients have been limited to the use of warfarin to reduce their risk of stroke. Whilst warfarin has been shown to reduce the risk of stroke in atrial fibrillation patients by 64 percent when compared with placebo², it has significant limitations.

It is well documented that patients find it hard to cope with the restrictions imposed on them under a warfarin regime, namely:

- Regular monitoring
- Stable diet
- Dosage manipulation.

These factors require constant interruption to the patient's daily routine, activities and livelihood; and can significantly impact their quality of life.

Approximately 80 000 Australians diagnosed with atrial fibrillation who are moderate to high stroke risk and require anticoagulation therapy do not receive it³. A recent audit by the National Stroke Foundation found that 70 percent of stroke patients with atrial fibrillation were not taking anticoagulant therapy at the time of their stroke.

Having such low patient uptake and compliance with warfarin means that there are large numbers of patients with Atrial Fibrillation that expose themselves to the significant risk of stroke on a daily basis. It is one thing to have patients with atrial fibrillation in the community; however the social and economic landscape changes considerably when those patients have a stroke. The wide ranging effects of a stroke impact deeply into society from a family, carer, patient, rehabilitation service and economic perspective.

Future options for improving the health outcomes of patients with atrial fibrillation treated with anticoagulants.

In March 2011 the Pharmaceutical Benefits Advisory Committee determined dabigatran to be cost effective and recommended it be added to the Pharmaceutical Benefits Scheme for the prevention of stroke in patients with atrial fibrillation. The treatment is already accepted and in use by 50 countries worldwide, including the US, UK and Canada.

Findings from the RE-LY trial, involving more than 18 000 patients worldwide show that when compared to even well managed warfarin (i.e. INR 2-3):

² Hart RG *et al.* Meta-analysis: Antithrombotic therapy to prevent stroke in patients who have non-valvular atrial fibrillation. *Ann Intern Med* 2007; 146(12):857-67.

³ Deloitte Access Economics. *Off beat: Atrial fibrillation and the cost of preventable strokes*. 2011.

- Dabigatran 150mg bd reduced the risk of stroke and systemic embolism by 35 percent without increasing the risk of major bleeding⁴
- Dabigatran 110mg bd was associated with a non significant 10 percent reduction of stroke and systemic embolism, however it is also associated with a significant 20 percent reduction in the risk of major bleeding⁵
- One of the most significant complications of anticoagulation therapy, namely intracranial bleeding, was significantly reduced with both doses of dabigatran.⁶

In addition to these clinical benefits, dabigatran also offers significant practical benefits and potential improvements to the quality of living for atrial fibrillation patients. It is hoped that this would lead to the uptake of treatment in a large number of atrial fibrillation patients who currently remain untreated and at high risk of stroke.

There is a high risk that the rate of stroke may rise in Australia for the first time in decades due to the increasing incidence of atrial fibrillation and limitations of older stroke prevention therapies, namely warfarin. Medical experts cite findings from the Deloitte Access Economics Report, “Off Beat: The Case for 21st Century Stroke Prevention” which concludes that up to 5700 strokes could be prevented each year by treating hitherto untreated patients with dabigatran.

This also points to the need for improved awareness of atrial fibrillation among the wider population of Australia. It is essential that we educate:

- Existing and future patients of the risk of leaving atrial fibrillation untreated
- The wider population about:
 - The need for regular health checks, include heart rate monitoring and the necessity of getting heart rate concerns checked by a medical professional
 - The impact of atrial fibrillation on the individual, family and society as a whole.

Financial considerations in adopting future options for improving the health outcomes of patients with atrial fibrillation treated with anticoagulants

One of the key factors in dabigatran not being directly released onto the PBS was the perceived cost of treatment. It can be shown that, the financial cost of dabigatran can be largely offset by:

- Reduction in clinical assessment, treatment time, materials and resourcing as the need for constant INR testing and monitoring is removed
- Reduction in total cost of treatment for atrial fibrillation related stroke
- Reduction in total cost of treatment for anticoagulant related intracranial bleed.

⁴ Connolly SJ, et al. Dabigatran versus Warfarin in Patients with Atrial Fibrillation. *N Engl J Med* 2009; 361:1139-51.

⁵ Connolly SJ, et al. Dabigatran versus Warfarin in Patients with Atrial Fibrillation. *N Engl J Med* 2009; 361:1139-51

⁶ Connolly SJ, et al. Newly identified events in the RE-LY trial. *N Engl J Med* 2010; 363(19): 1875-76.

Atrial fibrillation affects five percent of people aged 65 or over and the ten percent of those over 75. The IGR projects that over the next 40 years, the proportion of the population over 65 years will almost double to around 25 per cent.⁷ This represents a significant risk to both the Australian economy and the ability of Health Services to function effectively. With Australia's aging population, it is essential that the treatment options maximise uptake and successful clinical outcomes.

Recommendations:

1. Whilst there is a role for the continuation of warfarin based treatment, alternative options should be allowed for patients for whom warfarin is unsuitable either clinically or from an "effect on life" perspective.
2. It is suggested that, as part of the ongoing campaign to improve treatments and outcomes for atrial fibrillation sufferers the wider population becomes more informed about atrial fibrillation. An awareness campaign is needed to:
 - Improve understanding and outcomes for those who are currently being treated
 - Improve wider awareness of the condition and its impact.

Paceline would like to be a part of this solution and would be happy to work with interested parties to broaden Australia's understanding of Atrial Fibrillation.

3. We recommend that dabigatran be listed on the PBS as soon as possible and that future treatment options for atrial fibrillation are speedily considered in recognition of the increasing pervasiveness and wide ranging consequences of the condition.

Conclusion

New treatments for sufferers of any disease are few and far between and therefore invoke enormous emotion when they are delivered the public domain. To have a treatment such as dabigatran, that is readily available and improves on the treatment outcomes of warfarin both clinically and from a quality of life perspective, must surely weigh heavily against any economic benefits to be obtained by withholding the treatment. At Paceline, we see and hear the impact that atrial fibrillation has on peoples' lives, and therefore we ask that you consider giving sufferers this option to live and live well.

⁷ Australia's Demographic Challenges. Commonwealth of Australia, 2004