Atrial fibrillation (AF) is recognized as the most common cardiac arrhythmia encountered in clinical practice, affecting approximately 1–2% of the population. An estimated 6 million patients in Europe and 2.7 million patients in the USA suffer from AF. The actual prevalence of AF is higher, since these numbers reflect only clinically recognized, symptomatic AF.

The risk of developing AF increases with age, from <1% in those younger than 60 years to nearly 20% in patients older than 85 years (Fig 2). Hospital admissions for AF have increased 60% over the past 20 years and the prevalence of AF is estimated to double by 2050 due to the aging of the world’s population.

Disease registries are an effective tool to observe the course of a disease and treatment effectiveness and safety, to understand treatment variations in the outcomes and to examine the factors that affect survival, functionality, and quality of life. By collecting real-life data, registries can be used to describe care patterns, monitor safety and harm improvement.

Specifically when evaluating new drugs, the collection of real-life data is important for studying large patient numbers in a broad population with respect to various comorbidities and co-medications. A registry can provide supplementary data to data collected in randomized clinical trials with generally more strict inclusion criteria and dictated monitoring schemes. For a disease like AF and treatments like VKAs which require careful monitoring and dose adjustment the collection of real life data in a registry is particularly important considering that such treatments often perform well in clinical trials, however, the real world evidence for effectiveness does not match that observed in experimental studies.

The GLORIA-AF Registry Program is a large, international, observational study designed to characterize newly diagnosed patients with non-valvular atrial fibrillation at risk for stroke in different regions of the world. With up to 2200 participating sites and 50 countries, the Registry Program will increase the knowledge on the patient population and on the treatment choices selected when the patient is diagnosed with non-valvular AF and will collect data on safety and outcome events of current and future long-term antithrombotic strategy for stroke prevention in a real-world setting.

To reflect the real world setting sites participating in GLORIA-AF will range from general practice, specialist office, community hospital, university hospital to outpatient care center and anticoagulation clinics. Patients enrolled in the registry are newly diagnosed with non-valvular AF and each patient is at risk for stroke with one or more risk factors as defined by the CHA2DS2-VASc score of at least 1 (Fig 6B). Additionally, each patient’s risk for stroke will be assessed by the CHADS2, Stroke Risk Score and other scores to evaluate the bleeding risk of a patient 11,12. Taken together the data from the GLORIA-AF Registry Program will further the scientific knowledge on the long-term antithrombotic therapy for stroke prevention and contribute to the management on patients with atrial fibrillation in clinical practice.

**CURRENT THERAPEUTIC CHOICES**

Most cases of stroke due to AF are preventable by the use of antithrombotic therapy. A meta-analysis of all well-controlled trials demonstrated that warfarin decreased the risk of stroke/systemic embolism on average by 62% versus placebo, while aspirin therapy reduced the occurrence of stroke by 22% compared to placebo. When the analysis is confined to “aspirin-only” trials, aspirin reduces stroke by a non-significant 19% (95% CI: 1% to 35%) compared to placebo. Therefore, Vitamin K antagonists (VKAs) are currently the standard of care for stroke prevention in AF patients with a moderate to high risk of stroke, with warfarin being the most frequently prescribed VKA.

Despite the clinical benefits of VKAs, as demonstrated in clinical trials, there are significant challenges associated with their use:
- narrow therapeutic window
- variable and unpredictable dose-response effect
- numerous drug-drug and drug-food interactions
- slow onset and offset of action

**NEW ORAL ANTI_COAGULANT THERAPIES**

In order to address the shortcomings of VKAs, multiple new oral anticoagulants are in the late stages of clinical development including mainly direct thrombin and -factor Xa inhibitors. The most advanced new oral anticoagulants in the indication “stroke prevention in patients with atrial fibrillation” is the direct, reversible thrombin inhibitor dabigatran etexilate, which has recently been approved in the United States, Canada and Japan and is expected to be approved in a number of other countries around the world in 2011 and 2012. Dabigatran etexilate has been shown to significantly reduce the occurrence of stroke (both ischemic and hemorrhagic) and systemic emboli as well as intracranial hemorrhage (ICH) compared to warfarin while having a comparable rate of major bleeding in an 18,113 patient clinical study (RE-LY).

The approval of this new oral anticoagulants and the other new oral therapies for the prevention of stroke in AF patients is expected to alter antithrombotic therapy on a global scale and change the management of patients with AF. Consequently, there is a need to understand how these newer agents are used in clinical practice and perform regarding outcomes in a real life setting.

**REFERENCES**

**USING A REGISTRY TO UNDERSTAND REAL-WORLD CLINICAL EFFECTIVENESS**

For example, in a retrospective study of patients with AF eligible for warfarin treatment, only 15% actually received warfarin and, among those patients who received warfarin, INR values were outside of the therapeutic range approximately half of the time. Only 15% of patients eligible for treatment with warfarin were receiving treatment within the therapeutic range.

GLORIA-AF: A Global Registry on Long-Term Oral Antithrombotic Treatment in Patients with Atrial Fibrillation

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