



Thrombosis Research Institute
Emmanuel Kaye Building
Manresa Road
Chelsea
London
SW3 6LR

Media Contact
Mary Coyle
Ogilvy PR Worldwide
Tel: +1-646-338-7410

NEWS RELEASE

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STROKE PREVENTION THERAPY USE LOW AMONG HIGH-RISK PATIENTS WITH ATRIAL FIBRILLATION (AF)

-- GARFIELD Registry Data presented at ESC CONGRESS 2011 provides unique picture of the real global burden of AF --

PARIS, 28 August 2011 – New data show that, worldwide, one in three patients with atrial fibrillation (AF) who are at high risk for stroke are not being prescribed anticoagulant therapy, particularly vitamin K antagonists (VKA) – medicines known to significantly lower stroke risk in these patients. The findings are from the first cohort of the GARFIELD (Global Anticoagulant Registry in the Field) – an innovative research initiative being conducted by the Thrombosis Research Institute (TRI) to understand the global burden of AF, a common condition in which the two small upper chambers of the heart (the atria) quiver rather than beat rhythmically and can lead to life-threatening complications, including stroke.

The first analysis of cohort one included 9,288 patients newly-diagnosed with AF and with at least one additional risk factor for stroke from 19 countries in the Americas, Europe, Asia, and Asia Pacific. Of these patients, 81 percent had a high risk for stroke based on a score ≥ 2 on CHA₂DS₂-VASc, a detailed assessment of stroke risk in AF patients based on eight known risk factors.¹ Treatment guidelines recommend that all patients with a CHA₂DS₂-VASc or a CHADS₂ risk score ≥ 2 be prescribed anticoagulation therapy with VKAs, unless contraindicated, for example because of a risk of excessive bleeding. Whilst 81 percent of newly diagnosed patients had a CHA₂DS₂-VASc risk score ≥ 2 , only 64 percent of the high-risk patients in this cohort received any anticoagulant therapy. According to CHADS₂, 55 percent of newly diagnosed patients were at high risk for stroke out of which 33 percent did not receive any anticoagulant therapy.

“We know that atrial fibrillation carries a significant stroke risk and anticoagulants can reduce that risk by more than 60 percent; however, GARFIELD data suggest a lower utilization than would be anticipated based on clinical trial evidence and current treatment guidelines,” said Professor Ajay Kakkar, Director of the TRI, and Professor of Surgery, University College London. “Too many patients remain unprotected, and understanding the reasons for this will help in the appropriate adoption of innovative strategies to prevent stroke and improve clinical outcomes.”

According to the treating physicians, among patients in the entire cohort:

- The main reason cited for patients not receiving VKAs was “physician choice” (37%); fewer

¹ CHA₂DS₂-VASc = congestive heart failure, hypertension, age ≥ 75 (doubled), diabetes, stroke (doubled), vascular disease, age 65–74, and female gender

cited reasons such as low stroke risk (13%); excessive bleeding risk (7%) or history of previous bleeding event (2%)

- Overall 25% of patients were not prescribed an anticoagulant but received an antiplatelet drug such as aspirin alone which has proven less effective in lowering stroke risk in patients at high risk for stroke as an anticoagulant,¹ ; of these patients
 - 77% had a CHA₂DS₂-VASc ≥ 2
 - 49% had a CHADS₂ score ≥ 2
- In 13 percent of patients neither antiplatelet nor anticoagulant therapy were prescribed
 - 73% of these patients had a CHA₂DS₂VASC score ≥ 2
 - 43% of these patients had a CHADS₂ score ≥ 2

"GARFIELD is the largest, global disease registry that will provide us with a unique real-world view of the effectiveness and impact of current and future AF management," said Professor Jean-Pierre Bassand, Professor of Cardiology at the University of Besançon Franche-Comté. "GARFIELD is a prospective Registry in which clinical sites are going to be representative of national care settings who are managing AF patients in the long term. This will allow us to get a most complete view on how AF is being managed in real-world clinical practice rather than in expert centers and experienced research sites."

About GARFIELD

The GARFIELD Registry will prospectively follow 50,000 patients over a multi-phase six-year period. These individuals will be patients newly-diagnosed with AF and at least one additional risk factor for stroke who also are candidates for anticoagulant therapy to prevent blood clots leading to stroke. It will be left to the investigator's clinical judgment to identify patient's stroke risk factor(s). Data from an additional 5,000 patients with an AF history of at least 6 and no more than 24 months will be retrospectively analyzed and will be followed up prospectively until 24 months of data have been collected for each patient. GARFIELD will ultimately enroll patients from at least 1,000 centers in 50 countries in the Americas, Eastern and Western Europe, Asia, Africa and Australia.

Recruitment for the second cohort of the GARFIELD Registry will begin in September 2011, with baseline data to be available in 2012.

GARFIELD is a prospective Registry in which clinical sites are randomly selected to participate, avoiding selection of only sites expert in AF management in order to provide a real-world view of how AF is being managed in all care settings. At each site, consecutive newly-diagnosed patients will be entered into the Registry to avoid potential selection bias. All patients will be – according to their risk profile and guidelines – candidates for long-term anticoagulant stroke prevention therapy; they will be included whether or not they receive anticoagulant therapy so the true burden of disease including current and future treatment strategies and failures can be properly understood.

Data are being collected over a six-year period, and will include the following measures: thromboembolic stroke; transient ischemic attacks (TIA, or "mini-strokes"); blood clots affecting other areas of the body; bleeding events; therapy persistence (rate of and reason for discontinuation or duration of therapy); mortality; and major adverse cardiac events.

Among patients treated with anticoagulant therapy, additional outcomes data also will include the frequency and timing of monitoring required to maintain a safe and therapeutically-effective dose of anticoagulant and interventions required to manage complications due to anticoagulation therapy.

GARFIELD also includes health economic data to determine the true costs of AF globally and in each country participating, as well as a program to assess patient-reported outcomes with regard to the experience of their treatment.

The Registry is made possible through a research grant from Bayer Healthcare.

The Burden of AF

As much as one to two percent of the population has AF. Over 6 million Europeans suffer from this arrhythmia, and it is estimated that its prevalence will at least double in the next 50 years as the population ages, reaching more than 12 million. Around 4.5 million people in the European Union and 2.2 million people in the United States have AF, and estimates suggest that by 2014 more than 12 million people in the Asia-Pacific region will have AF.^{2,3,4,5} AF confers a 5-fold increase in the risk of stroke, and one in five of all strokes is attributed to this arrhythmia. Ischemic strokes in association with AF are often fatal, and those patients who survive are left more frequently and more severely disabled by their stroke and more likely to suffer a recurrence than patients with other causes of stroke. In consequence, the risk of death from AF-related stroke is doubled and the cost of care is increased by 50%. The condition occurs when parts of the atria emit uncoordinated electrical signals that cause the chambers to pump too quickly and irregularly, thereby not allowing blood to be pumped out of the atria completely.¹ As a result, blood may pool, clot and lead to thrombosis, which is the number one killer in both the developed and developing world.

If a blood clot leaves the left atrium, then it could potentially lodge in an artery in other parts of the body, particularly in the brain. A blood clot in an artery in the brain leads to a stroke. In fact, 92 percent of fatal strokes are caused by thromboses.⁶ People with AF are not only at a five times higher risk of suffering a stroke than the general population, but they are also at high risk for heart failure, chronic fatigue and other heart rhythm problems.^{7,8} Stroke is a major cause of long-term disability worldwide – each year 5 million stroke sufferers are left permanently disabled.⁹

About the Thrombosis Research Institute (TRI)

TRI is a charitable foundation and multi-disciplinary research institute dedicated to the study of thrombosis and related disorders. TRI's mission is to provide excellence in thrombosis research and education; to develop new strategies to prevent and treat thrombosis; and thereby improve quality of care, advance clinical outcomes and reduce healthcare costs. The TRI is a member of University College London Partners Academic Health Science System.

For more information, visit <http://www.tri-london.ac.uk/>.

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⁹ The Cleveland Clinic. Diseases & Conditions: What is atrial fibrillation? Available at: http://my.clevelandclinic.org/heart/atrial_fibrillation/afib.aspx