

MEDIA INFORMATION

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Real-world evidence from the GARFIELD registries provides important insights to aid understanding of the outcomes of anticoagulation

- *Data highlighted differences between provoked and unprovoked venous thromboembolism (VTE) patients.*
- *Other topics included the comparative effectiveness of vitamin-K antagonists (VKAs) and direct oral anticoagulants (DOACs) in VTE and atrial fibrillation (AF), cancer-associated thrombosis and regional differences in VTE.*

Melbourne, Australia, 8th July 2019 – The depth and breadth of real-world evidence available from the Global Anticoagulant Registry in the FIELD (GARFIELD) studies was evident as the Thrombosis Research Institute (TRI) unveiled its latest results during a supported Satellite Symposium at the International Society on Thrombosis and Haemostasis Congress 2019, on Saturday 6th July.

The Symposium, entitled “Understanding the Outcomes of Anticoagulation: Insights from the GARFIELD Registries”, featured a distinguished speaker panel of clinical leaders who shared insights on a wide range of topics pertinent to modern thrombosis management. Topics included perspectives on provoked versus unprovoked VTE; comparative effectiveness in both AF and VTE, cancer-associated thrombosis (CAT) in everyday practice; and regional differences in VTE.

Rt Hon Professor the Lord Ajay K. Kakkar, Director of the Thrombosis Research Institute, UK, said: “Our analysis of the real-world evidence collected in the GARFIELD registries enable us to show physicians how the treatment decisions made during everyday practice around the world are impacting patients’ outcomes. The scale of our registries and the methodological rigour we apply mean that these data can be trusted to help inform and enhance understanding and influence treatment guidance across the globe.”

Examining the differences between provoked and unprovoked VTE, Professor Walter Ageno (Varese, Italy) said that VTE patients with transient provoking risk factors were more likely to be younger, and female, than patients with unprovoked VTE. Furthermore, anticoagulant treatment at baseline was similar between patients with transient provoking factors and unprovoked VTE. However, on average, patients with an unprovoked VTE remained on anticoagulant treatment longer than those with a provoked VTE. “Event rates were comparable between patients with transient provoking factors and unprovoked VTE. Patients with a persistent provoking factor (i.e. active cancer) had an increased incidence of death and major bleeding,” Professor Ageno commented.

Professor Harry Gibbs (Melbourne, Australia) delved into the topic of comparative effectiveness in AF. He told delegates that patients receiving an oral anticoagulant were at a significantly reduced risk of mortality over 2 years follow-up, compared to patients receiving no OAC, after adjustment for baseline variables. Furthermore, patients receiving a non-vitamin K antagonist oral anticoagulant (NOAC) were at a reduced risk of death compared to those receiving a vitamin K antagonist (VKA). Patients on oral anticoagulant (OACs) versus those on no anticoagulants also had a significantly lower risk of stroke/systemic embolism but a higher risk of major bleeding over the 2 years of follow-up. “These observations suggest that the effectiveness of OACs in randomised clinical trials can be translated to the broad cross-section of patients treated everyday practice.” Professor Gibbs concluded.

Professor Alexander G. Turpie (Hamilton, Canada), speaking on comparative effective from a VTE perspective, highlighted that patients receiving NOACs had a significantly reduced chance of all-cause mortality over 12-months follow up. He added that recurrent VTE and major bleeding was not significantly different between the treatment groups. “Our future work will focus on assessing the impact of treatment adherence and duration on outcomes” he revealed.

GARFIELD-VTE highlights differences in the treatment patterns of VTE in patients with active cancer, history of cancer or no cancer. Speaking about CAT in everyday practice, Professor Jeff Weitz (Hamilton, Canada) said that rates of death, recurrent VTE and major bleeding were higher in active cancer patients than in those without cancer. He told delegates that the majority of deaths were cancer-related; VTE was the second leading cause of death in both active cancer and history of cancer patients.

Professor Barry Jacobson (Johannesburg, South Africa) presented several differences in baseline characteristics between Europe, Asia, North America and Australia, Latin America, and South Africa and the Middle East, such as the ratio of males to females, the site of VTE, as well as age, BMI and ethnicity. He said that future studies will investigate how these differences may influence clinical outcomes in patients.

GARFIELD-VTE is a prospective, multicentre, observational study of patients with acute VTE. The registry has enrolled more than 10,000 patients with deep vein thrombosis and/or pulmonary embolism from 415 sites in 28 countries. The aim of this global registry is to follow patients for at least three years and to observe patients’ management according to local practices, recording clinical, patient-reported and economic outcomes.

GARFIELD-AF is the largest global prospective registry of patients with AF. It aims to enhance the breadth and depth of understanding stroke prevention in AF, ultimately informing strategies to improve patient outcomes, safety, and utilisation of healthcare resources. To date, it has generated at least 2 years of follow-up data in over 57,000 patients with newly diagnosed AF.

About GARFIELD-VTE

GARFIELD-VTE is a prospective registry describing acute and long-term management and outcomes in 10,874 adult patients with venous thromboembolism (VTE) representative of everyday clinical practice in 28 countries.

It is an international, observational, multicentre study of patients with newly diagnosed VTE. Patients were enrolled from 415 sites from 28 countries worldwide, including the Americas, Europe, Africa and Asia-Pacific. Compared with other ongoing prospective registries in VTE, GARFIELD-VTE has the potential to capture the burden of disease in large-scale populations by employing broad inclusion criteria in widely representative populations of patients with VTE (across a range of clinical settings) and to capture long-term follow-up data in the community as well as the hospital setting.

Contemporary understanding of VTE is based on data gathered in controlled clinical trials. Whilst essential for evaluating the efficacy and safety of new treatments, these trials are not representative of everyday clinical practice and, hence, uncertainty persists about the real-life burden and management of this disease. GARFIELD-VTE seeks to provide insights into the impact of anticoagulant therapy on thromboembolic and bleeding complications seen in this patient population. It will provide a better understanding of the potential opportunities for improving care and clinical outcomes amongst a representative and diverse group of patients and across distinctive populations. This should help physicians and healthcare systems to appropriately adopt innovation to ensure the best outcomes for patients and populations.

Current treatment regimens in real-life practice seem to be shorter than recommended guidelines¹. GARFIELD-VTE is important in connecting research and clinical practice, serving to increase awareness of the importance and treatment of DVT/PE.

The registry seeks to describe:

- the acute, sub-acute and extended duration of anticoagulation management;
- the clinical and economic outcomes in patients with treated acute VTE in the real-world setting.

The registry started in July 2014. Four key design features of the GARFIELD-VTE protocol ensure a comprehensive and representative description of VTE; these are:

- Two sequential cohorts of prospective, newly diagnosed patients, facilitating comparisons of discrete time periods and describing the evolution of treatments and outcomes;
- Selection of sites representative of national VTE care settings;
- Enrolment of consecutive eligible patients regardless of therapy to eliminate potential selection bias;
- Follow-up data captured for a minimum of 36 months after diagnosis, to create a comprehensive database of treatment decisions and outcomes in everyday clinical practice.

Patients are included whether or not they receive anticoagulant therapy, so that the merit of current and future treatment strategies can be properly understood in relation to patients' individual risk profiles.

The GARFIELD-VTE registry is supported by an unrestricted educational grant from Bayer AG, Berlin, Germany.

For further information, please visit: www.garfieldregistry.org.

The burden of VTE

VTE occurs when part of a clot formed in a deep vein, for example in the leg (known as deep vein thrombosis, or DVT), is carried to the lung, via the heart, preventing the uptake of oxygen. This is known as a pulmonary embolism (PE), an event which can be rapidly fatal.

The third most common cardiovascular illness after acute coronary syndrome and stroke, VTE is responsible for nearly 800,000 deaths in the Europe and United States each year. This equates to VTE killing one person every 37 seconds in the Western world. In around 90% of fatal cases the embolism is undetected or untreatable. VTE recurrence is likely, making VTE-prevention an essential task for every healthcare system^[i].

Approximately 20% of all VTE cases occur in patients with cancer, and VTE is present in up to 50% of patients with cancer at autopsy^[ii]. The total cost of VTE treatment and management is estimated to be £640 million per year in the United Kingdom ^[iii]. Like its sister registry GARFIELD-AF, GARFIELD-VTE will be vital in improving clinical practice in the coming years.

About TRI

The Thrombosis Research Institute (TRI) is dedicated to bringing new solutions to patients for the detection, prevention and treatment of blood clots. The TRI's goal is to advance the science of real-world enquiry so that the value of real-world data is realised and becomes a critical link in the chain of evidence. Their pioneering research programme, across medical disciplines and across the world, continues to provide breakthrough solutions in thrombosis.

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

References

^[i] GARFIELD-VTE Registry. About VTE. Available at <https://vte.garfieldregistry.org/about/about-vte> [Accessed: 1 July 2019]

^[ii] Lyman G. Venous Thromboembolism in the Patient with Cancer: Focus on Burden of Disease and Benefits of Thromboprophylaxis. *Cancer*. 2011 Apr 1; 117(7): 1334–1349.

^[iii] Ageno W, McCallum P, Haas S, et al. Clinical characteristics and management of 10,329 patients with a confirmed diagnosis of venous thromboembolism: the GARFIELD-VTE registry. Oral presentation at ISTH Congress 2017.