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The GARFIELD-VTE Registry's first-ever results presented at the ISTH 2017 Congress shed light on a wide heterogeneity of VTE patients across the globe, their treatment and outcomes

- *With uniquely broad inclusion criteria, the registry covers diverse populations of patients with VTE across a range of clinical settings and countries*
- *As a prospective registry undertaking long-term follow-up, GARFIELD-VTE will provide unprecedented data on extended anticoagulation therapy and bridge randomised pivotal trial data with real-world considerations*
- *Six-month outcomes results demonstrate that death was the most frequent major adverse outcome, and 54.3% of these were cancer-related*

Berlin, Germany, 12th July 2017 – The first results from the Global Anticoagulant Registry in the Field - Venous Thromboembolism (GARFIELD-VTE) were presented at the International Society on Thrombosis and Haemostasis (ISTH) Congress 2017, in Berlin, Germany this week, providing a contemporary picture of VTE management worldwide.

GARFIELD-VTE is a prospective, multicentre, observational study of patients requiring treatment for acute VTE. The registry enrolled more than 10,000 patients with acute VTE [deep vein thrombosis (DVT) and pulmonary embolism (PE)] from across 415 sites in 28 countries between May 2014 and January 2017. Study sites reflect the diversity of care settings in each country, including hospital, outpatient and community settings, making this study uniquely placed to provide data on several subsets of VTE patients, including those with recurrent VTE, post-thrombotic syndrome and chronic thromboembolic pulmonary hypertension.

The aim of this global registry is to follow patients for at least three years and to observe patients' management according to local practices and to record clinical, patient-reported and economic outcomes. The first data from GARFIELD-VTE offer fresh insights into the clinical characteristics, treatment patterns and outcomes of VTE patients, including those with cancer.

"For patients with DVT and PE, fast action in the acute phase of treatment, especially rapidly fatal PEs, is vital for preserving life and health. As a global registry collecting long-term data from diverse countries, care settings and patients, GARFIELD-VTE is able to provide unprecedented insights on managing and improvement patient care," said Rt Hon Professor the Lord Ajay K Kakkar, Professor of Surgery at University College London and Director of the Thrombosis Research Institute, UK.

Clinical characteristics and management

In an oral presentation today, Dr Walter Ageno, Associate Professor of Medicine at the University of Insubria and Director of the Short-Stay Medical Unit and Thrombosis Center at the Ospedale di Circolo of Varese, Italy, presented data[i] on the clinical characteristics and

management of 10,677 patients with a confirmed diagnosis of DVT and/or PE enrolled in GARFIELD-VTE. Surgery (12.5%) and hospitalisation (12%) were the main provoking risk factors. The analysis demonstrated that treatment patterns are rapidly evolving. The direct oral anticoagulants (DOACs) were prescribed to about half of the patient population, in similar proportions between DVT and PE, and PE patients were more likely to receive initial parenteral treatment with low molecular weight heparin (LMWH).

Cancer-associated thrombosis

On Monday, data seen during a poster session led by Professor Jeff Weitz, Professor of Medicine and Biochemistry and Biomedical Sciences at McMaster University, Hamilton, Ontario, Canada, highlighted the differences in the treatment patterns of VTE in patients with active cancer compared to those with a history of cancer or no cancer. The most common sites of cancer-associated thrombosis are lung (in men) and gynaecological (in women). Patients with active cancer (56.1%) were more likely to receive LMWH as initial therapy than those with a history of cancer (15.9%) or no cancer (9.2%)[ii]. DOACs with or without LMWH were prescribed in almost 27% of patients.

Treatment patterns

Yesterday, Professor Sylvia Haas, Emeritus Professor of Medicine of the Haemostasis and Thrombosis Research Group, Technical University of Munich, Munich, Germany, spoke about anticoagulant treatment patterns for VTE[iii]. She said that the variation of initial AC treatment patterns during enrolment of patients is less than originally expected because momentum in DOACs prescribing had already taken hold when GARFIELD-VTE started. Where variations are seen, said Professor Haas, these are based not only on patient population and site of VTE but also by geographic region, and may reflect cultural differences as well as registration and reimbursement of DOACs. There was a clear shift from conventional parenteral plus VKA treatment in the first 30 days towards DOACs in the following 5 months, raising the question about whether DOACs have become the new standard of care for chronic anticoagulation.

Six-month outcomes

Presenting the Registry's first six-month outcomes data[iv], Professor Alexander GG Turpie, Professor Emeritus, McMaster University, Hamilton, Ontario, Canada, reported that rates of all-cause mortality, first occurrence of major bleeding and VTE recurrence were: 9.7 (8.8 to 10.6), 2.2 (1.9 to 2.7), and 3.6 (3.1 to 4.2) per 100 person-years, respectively. Overall, 106 of 622 (17.0%) bleeds were major, requiring transfusion in 90 (14.5%) cases. Fatal bleeding occurred in 15 of 622 (2.4%) patients with any bleeding event. One hundred and ninety-five new cases of cancer were detected over 6 months which is equivalent to a rate of 4.1 per 100 person-years. Death was the most frequent major adverse outcome in patients with VTE, half of which were cancer-related.

The next set of GARFIELD-VTE data will be presented at the American Society of Hematology (ASH) Congress, in Atlanta, from 9th to 12th December 2017.

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About the GARFIELD-VTE registry
GARFIELD-VTE is a prospective registry describing acute and long-term management and outcomes in 10,878 adult patients with venous thromboembolism (VTE) representative of everyday clinical practice.

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, between May 2014 and January 2017. Compared with other ongoing prospective registries in VTE, the global GARFIELD-VTE registry has the potential to capture the burden of disease in large-scale populations by employing broad inclusion criteria in a 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 guidelines[1]. 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.

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 600,000 to 700,000 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[v].

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[vi]. The total cost of VTE treatment and management is estimated to be £640 million per year in the United Kingdom[i]. Like its sister registry GARFIELD-AF, GARFIELD-VTE will provide will be vital in improving clinical practice in the coming years.

About the 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/.

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[i] 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.

ii Weitz JI, Turpie AGG, Haas S, et al. Clinical characteristics and treatment of patients with cancer-associated venous thromboembolism: Results from the GARFIELD-VTE registry. Poster presented at ISTH Congress 2017.

[iii] Haas S, Turpie AGG, Weitz JI, et al. Anticoagulation treatment patterns of venous thromboembolism in GARFIELD-VTE patients. Poster presented at ISTH Congress 2017.

iv Turpie AGG, Haas S, Weitz JI, et al. 6-months outcomes of patients: Results from GARFIELD-VTE. Poster presented at ISTH Congress 2017.

v GARFIELD-VTE Registry. About VTE. Available at http://vte.garfieldregistry.org/about/about-vte [Accessed: 5 June 2017]

[vi] Thrombosis Advisor. VTE in Patients with Cancer. Available at https://www.thrombosisadviser.com/VTE-in-Patients-with-Cancer/. [Accessed: 5 June 2017]