



# About Thrombosis

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## What is Thrombosis?

Thrombosis is the formation of a clot inside a blood vessel, blocking a vein (**venous thrombosis**) or artery (**arterial thrombosis**).

Blood clots form to prevent bleeding in response to damage to a blood vessel; they act as a plug at the site of the blood vessel injury<sup>1</sup>. However, if the blood clotting cascade is inappropriately activated, this can lead to the formation of potentially deadly blood clots<sup>1</sup>.

A thromboembolism occurs when the blood clot breaks loose and is carried by the blood stream and obstructs the flow of blood in a vessel<sup>1</sup>.

## Why is Thrombosis Dangerous?

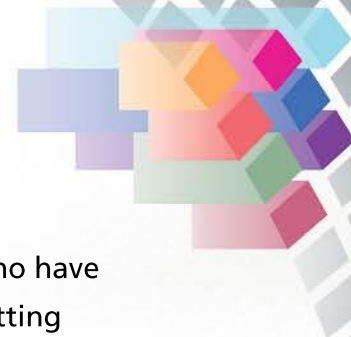
Thrombosis can lead to a range of venous and arterial thromboembolic (VAT) conditions which affect millions of people worldwide.

- ◆ **Venous thromboembolism (VTE)** encompasses two serious conditions - deep vein thrombosis (DVT) and pulmonary embolism (PE). DVT is a blood clot that forms in a deep vein, usually in the leg, which partially or totally blocks the flow of blood. If all or part of a DVT breaks off, it can be carried with the blood stream to the lungs via the pulmonary artery. Once there, it can block a blood vessel taking the blood to the lung. This critical condition is called pulmonary embolism (PE). In many cases, the first and last sign of a VTE is a sudden, fatal PE
- ◆ **Arterial thromboembolism** is linked to stroke, ischaemic heart disease and peripheral vascular disease. It can also lead to acute coronary syndrome (ACS), a term which covers unstable angina and heart attacks, also known as myocardial infarction

## Who is at Risk of Thrombosis?

Populations at risk of thrombosis include:

- ◆ **Venous thromboembolism (VTE):** Patients undergoing surgery, such as major orthopaedic surgery for hip or knee replacement, major surgery for cancer, as well as those admitted to hospital for an acute medical condition. Additionally, patient-related, or predisposing, risk factors include inherited thrombophilia, advanced age, obesity, prior VTE and varicose veins<sup>2</sup>

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- ◆ **Arterial thromboembolism:** Patients with atrial fibrillation (AF) and those who have survived a previous episode of ACS, including patients in the emergency care setting presenting with chest pain or other symptoms that might indicate ACS

## What is the Burden of Thrombosis?

### Mortality and morbidity

#### ◆ Venous thromboembolism (VTE):

- VTE kills one person every 37 seconds, which is more than 843,000 deaths every year<sup>3,4</sup>. This includes over 540,000 deaths in Europe alone<sup>5</sup>. In the EU, more than twice as many people die from VTE than from breast cancer, prostate cancer, AIDS and traffic accidents combined<sup>4</sup>
- 10–25% of PEs are rapidly fatal<sup>6,7</sup>, usually within 2 hours of the onset of symptoms

#### ◆ Arterial thromboembolism:

- Patients with AF have a fivefold increased risk of stroke, and AF-related strokes are more severe than in those without the condition<sup>8</sup>. Patients who suffer an AF-related stroke are 50% more likely to die within one year of the stroke<sup>8</sup>
- Coronary heart disease kills approximately 7.2 million people worldwide each year<sup>9</sup>, many of which are attributable to ACS

## How is Thrombosis Prevented and Treated?


Anticoagulants have been used for more than 70 years to prevent and treat potentially deadly blood clots, but widely used traditional therapies are associated with significant drawbacks.

#### ◆ Venous thromboembolism (VTE):

- The traditional standard therapy for **prevention of VTE** associated with orthopaedic surgery is a class of anticoagulant drugs known as heparins
- The current standard of care for **treatment and prevention of recurrent VTE** is the dual-drug approach of heparin followed by a vitamin K antagonist (VKA), such as warfarin

#### ◆ Arterial thromboembolism:

- The current standard of care for **preventing AF-related stroke** are vitamin K antagonists (VKAs)

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- The current standard of care for **preventing new blood clots in patients with ACS** is a dual antiplatelet therapy of aspirin plus a drug class known as thienopyridines

There are limitations associated with current therapies that may contribute to their under-utilisation<sup>10</sup>, creating challenges for patients and potentially leaving them at risk.

- ◆ Heparins require administration by injection, which can be inconvenient and cause discomfort. In addition, some patients taking heparin experience a severe reaction known as HIT (heparin-induced thrombocytopenia), which can lead to new or worsening thrombosis<sup>11</sup>
- ◆ VKAs have a narrow therapeutic window (meaning there is a small gap between the dose that provides effective anticoagulation and a dose that increases bleeding events or can increase the rate of blood clots), and therefore can require frequent dose adjustments and a need for routine coagulation monitoring. Furthermore, VKAs have a slow onset of action, as well as many food and drug interactions<sup>12,13</sup>
- ◆ Despite the efficacy of dual therapy with aspirin and thienopyridines, there is still a high rate of subsequent cardiac events following an ACS episode<sup>14</sup>

**New oral anticoagulants** hold the promise of overcoming the limitations of traditional anticoagulants, thereby enabling their use to prevent and or treat more VAT conditions.

- ◆ Benefits of new oral anticoagulants include predictable anticoagulation without the need for routine coagulation monitoring or frequent dose adjustment, low risk of drug-drug interactions and no dietary restrictions
- ◆ Xarelto® (rivaroxaban) is a highly effective, oral, anticoagulant developed to prevent and treat dangerous blood clots in a wide range of patient populations





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## About Rivaroxaban (Xarelto®)

Rivaroxaban is an oral anticoagulant that was discovered in Bayer HealthCare's Wuppertal laboratories in Germany, and is being jointly developed by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. It has a rapid onset of action with a predictable dose response and high bioavailability, no requirement for routine coagulation monitoring, and a limited potential for food and drug interactions.

Rivaroxaban is marketed under the brand name Xarelto® for VTE prevention in adult patients following elective hip or knee replacement surgery, and it is the only oral anticoagulant that has consistently demonstrated superior efficacy over enoxaparin in this indication. Rivaroxaban is approved in more than 110 countries worldwide and marketed outside the U.S. by Bayer HealthCare in this indication.

In the U.S., where rivaroxaban has been available since July 2011 for VTE prevention in adult patients following elective hip or knee replacement surgery, Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company) holds marketing rights. The Bayer HealthCare sales force is supporting Janssen Pharmaceuticals, Inc. in designated hospital accounts. On November 4, Xarelto® received further marketing approval in the U.S. for the prevention of stroke in patients with Atrial Fibrillation.

The extensive clinical trial programme supporting rivaroxaban makes it the most studied and widely published oral, direct Factor Xa inhibitor. The studies, reported and ongoing, involve over 75,000 patients for the prevention and treatment of venous and arterial thromboembolic (VAT) disorders across a broad range of acute and chronic conditions, including stroke prevention in patients with Atrial Fibrillation, DVT treatment and the prevention of recurrent DVT or PE, and the secondary prevention of Acute Coronary Syndrome.

**To learn more about thrombosis, please visit [www.thrombosisadviser.com](http://www.thrombosisadviser.com)**

**To learn more about 'Xarelto' please visit [www.xarelto.com](http://www.xarelto.com)**

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**RIVAROXABAN**