X-VeRT

PHASE IIIb

Once-daily Rivaroxaban shown to be an Effective Alternative to Vitamin K Antagonists (VKAs) with a Reassuring Safety Profile in the Clinical Management of Patients with Atrial Fibrillation (AF) who are Undergoing Elective Cardioversion

First Prospective Novel OAC Study in Patients With AF Undergoing Cardioversion

>1,500 Patients from 141 centres across 16 Countries

Phase IIIb Study: Addressing Unanswered Clinical Questions

Cardioversion is a medical procedure to help reset the heartbeat back to a regular rhythm[1]. This procedure is most commonly used in patients with AF[2] as up to 18.2% of these patients undergo cardioversion[3].

Patients with AF have an increased risk of blood clots forming in the left atrium of the heart. Cardioversion may knock these clots loose. If the clot travels (embolus) to the brain, it can cause a devastating stroke. To avoid this, patients scheduled for cardioversion are prescribed anticoagulants before and after the procedure[4]. Without adequate anticoagulation, these patients have a risk of thromboembolic complications with stroke rates of 5–7%[5].

Current Guidelines recommend at least three weeks of effective anticoagulation with VKAs (target INR 2.0-3.0) prior to cardioversion (or less if a transesophageal echocardiogram has revealed no left atrial or left atrial appendage thrombus) and four weeks of oral anticoagulation after the procedure.

However, unstable INR levels often result in cancellation or postponement of cardioversion. This speaks to the need for stable, effective anticoagulation in these patients to help prevent life-threatening blood clots before, during and after the procedure.[6]

New data from the X-VeRT Study presented at the ESC Congress 2014 and simultaneously published in the European Heart Journal confirms oral, once-daily rivaroxaban 20mg is an effective alternative to VKAs, such as warfarin, with a reassuring safety profile, in protecting patients with AF from potentially deadly blood clots when undergoing cardioversion while helping to reduce the risk of unstable anticoagulation or postponement of cardioversion.[5]

Efficacy Results

Once-daily rivaroxaban showed a numerical reduction of cardiovascular events by 50% in the composite primary efficacy outcome of stroke, transient ischemic attack, peripheral embolism, heart attack and cardiovascular death compared to VKA

Safety Results

Once-daily rivaroxaban demonstrated a numerical reduction in the risk of major bleeding by 24% compared to VKA, underscoring the reassuring safety profile of rivaroxaban seen in other phase III studies

The study was designed to support previous findings of rivaroxaban in the setting of cardioversion from ROCKET AF and was not powered for statistical significance.

Rivaroxaban shortened the time to cardioversion compared with VKA, providing practical advantages that may have the potential to reduce healthcare costs.

When taken as prescribed, rivaroxaban provided more reliable anticoagulation prior to cardioversion than VKA, which will reduce the number of cancelled cardioversion procedures in clinical practice.

The extensive evaluation of rivaroxaban to protect different patient populations at risk of venous and arterial thromboembolism (VAT), makes it the most studied novel OAC in the world. Rivaroxaban (Xarelto®) is already approved for five indications in seven areas of use and its investigation - both completed and ongoing - will include more than 275,000 patients in clinical trials and real world settings.

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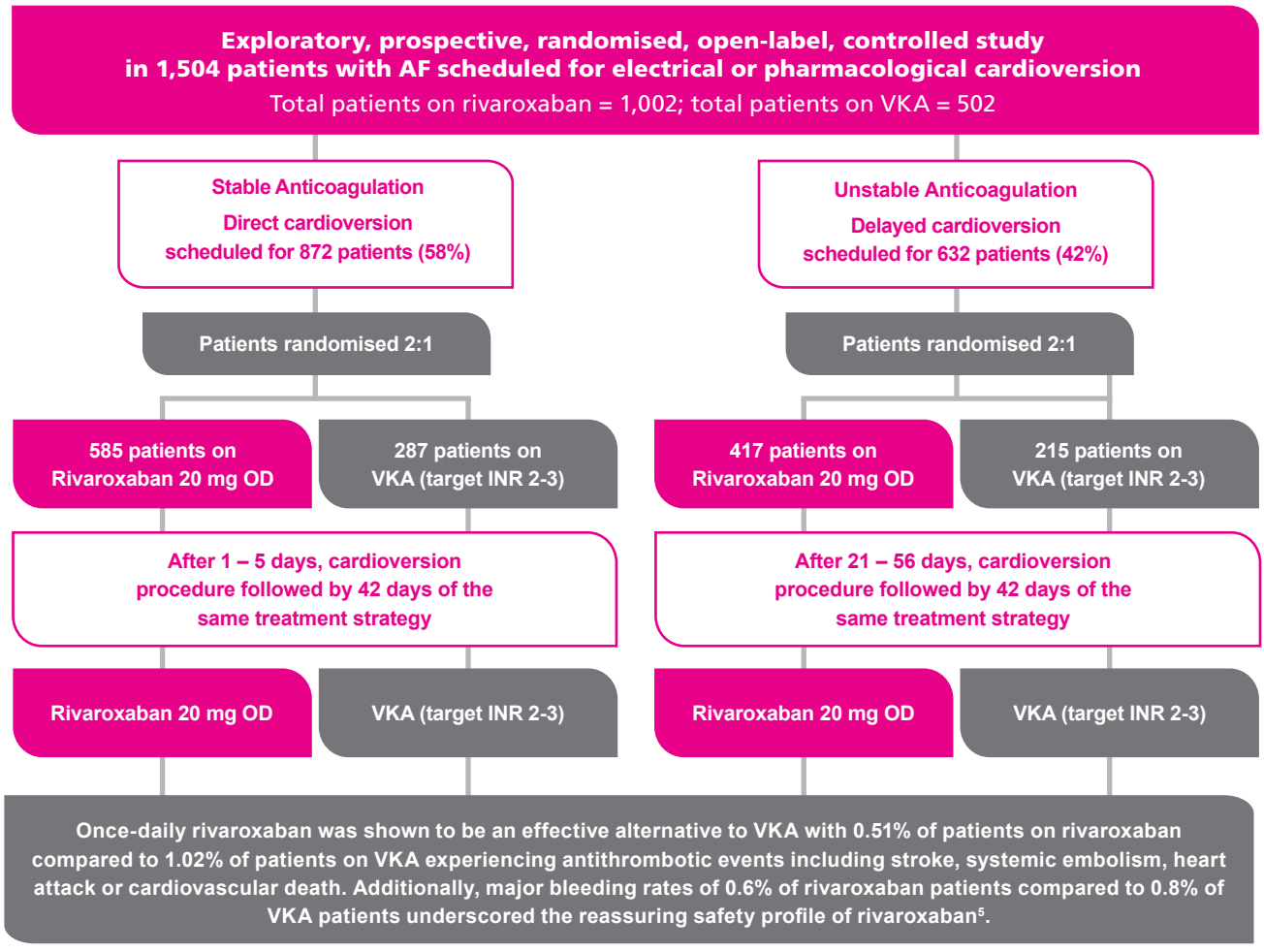
The X-VeRT Study was Uniquely Designed to Include Both Direct (or Early) and Delayed Cardioversion Strategies

The Study[5]

When physicians and patients are considering the option of cardioversion, the time since the patient was diagnosed with AF and the patient's risk of stroke is taken into account in order to determine whether the direct or delayed cardioversion strategy is implemented. In the X-VeRT Study, the physician determined the cardioversion strategy while the treatment strategy was assigned.



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