Rivaroxaban reduces length of hospital stay in patients with symptomatic venous thromboembolism

The phase III EINSTEIN deep vein thrombosis (DVT) and EINSTEIN pulmonary embolism (PE) trials demonstrated the potential of oral rivaroxaban (Xarelto, Bayer) – 15 mg twice daily for 21 days, followed by 20 mg once daily – for the treatment of venous thromboembolism (VTE), a term that embraces DVT and PE. A subsequent study by van Bellen *et al.*,[1] published in *Current Medical Research and Opinion* in 2014, was undertaken to assess the length of initial hospitalisation in patients presenting with either symptomatic DVT or PE using hospitalisation records from these trials.

The authors found that overall 52% of EINSTEIN DVT patients and 90% of EINSTEIN PE patients were admitted to hospital. The proportion of hospitalised DVT patients with a length of stay 5 days or fewer, receiving rivaroxaban, was 54% compared with 31% for those receiving enoxaparin/vitamin K antagonist (VKA), the current standard of care for the treatment of patients with symptomatic DVT and PE. For patients with PE, the corresponding values were 45% and 33%. Stays of 6 - 10 days were observed in 29% of rivaroxaban-treated patients compared with 45% for enoxaparin/VKA-treated patients for DVT. For patients with PE, these values were 39% and 46% in the rivaroxaban and enoxaparin/VKA groups, respectively. Overall, length of stay was significantly shorter in the rivaroxaban group, compared with the enoxaparin/VKA group across all analyses performed ($p<0.0001$).

VTE is associated with significant morbidity and mortality and therefore carries a considerable healthcare burden. Rivaroxaban is as effective as enoxaparin/VKA for the treatment of acute symptomatic DVT or PE, with the additional benefit of significantly reducing the period of hospitalisation in patients being treated for an initial DVT or PE. 'Coupled with improved patient treatment satisfaction and no requirement for routine monitoring or dose adjustment, this presents strong advantages for treating patients with VTE with rivaroxaban,' the authors wrote. They concluded that a single-drug regimen with rivaroxaban may reduce the burden on healthcare systems and patients by providing effective and well-tolerated treatment. 'The convenience of a single-drug approach with oral rivaroxaban has the potential to allow discharge based on a patient's clinical condition and to facilitate the transition from in-hospital to outpatient care. […] However, assessment of patient risk is still warranted to identify candidates who can safely receive outpatient treatment, and patient monitoring is essential to ensure adherence to the specified dosing regimen.'

Reference

1. van Bellen B, Bamber L, Correa de Carvalho F, et al. Reduction in the length of stay with rivaroxaban as a single-drug regimen for the treatment of deep vein thrombosis and pulmonary embolism. Curr Med Res Opin 2014; 30(5):829-837. [http://dx.doi.org/10.1185/03007995.2013.879439]

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Reference: 1. Laube BL, Janssens HM, de Jongh FHC, et al. What the pulmonary specialist should know about the new inhalation therapies. Eur Respir J 2011;37:1308-1331.

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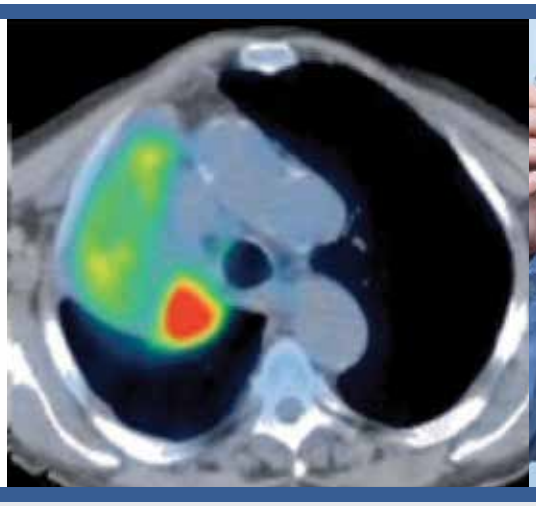


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Starting dose should be appropriate for severity of the disease. Dose may be adjusted until control is achieved or reduced to the minimum effective dose, according to the individual response. **Children over 6 years of age:** 50-100 µg twice daily. The dose may be adjusted until control is achieved and should be reduced to the minimum effective dose according to the individual response. **Special patient groups:** No dose adjustment in elderly patients. **For the transfer of patients being treated with oral corticosteroids:** Patients treated with systemic steroids for long periods of time or at a high dose may have adrenocortical suppression and adrenocortical function should be monitored regularly and their dose of systemic steroid reduced cautiously. After approximately a week, gradual withdrawal of the systemic steroid may be commenced. Decrements in dosages should be appropriate to the level of maintenance systemic steroid, and introduced at not less than weekly intervals. In some patients on oral corticosteroids the dose reduction or replacement with inhaled corticosteroids may not be possible. Some patients feel unwell in a non-specific way during the withdrawal phase despite maintenance or even improvement of the respiratory function. They should be encouraged to persevere with inhaled fluticasone propionate and to continue withdrawal of systemic steroid, unless there are objective signs of adrenal insufficiency. **SIDE EFFECTS AND SPECIAL PRECAUTIONS:** Treatment should not be stopped abruptly as adrenal insufficiency may be precipitated. Candidiasis of the mouth and throat (thrush) may occur. May be helpful to rinse out mouth with water after use. Symptomatic candidiasis can be treated with topical anti-fungal therapy whilst continuing treatment. Hoarseness. Paradoxical bronchospasm with an immediate increase in wheezing. Treat immediately with a fast-acting inhaled bronchodilator. Treatment should be discontinued immediately, the patient assessed, and if necessary alternative therapy instituted. Cutaneous hypersensitivity. Systemic corticosteroid effects may occur. Patients transferred from other inhaled steroids or oral steroids remain at risk of impaired adrenal reserve for a considerable time after transferring to inhaled fluticasone propionate. Increasing use to control symptoms indicates deterioration of asthma control and patient should be reassessed. Sudden and progressive deterioration in asthma control is potentially life-threatening and may have several causes. Consideration should be given to increasing corticosteroid dosage if not caused by otherwise treatable causes of deterioration. Severe asthma requires regular medical assessment as death may occur. Sudden worsening of symptoms may require increased corticosteroid dosage which should be administered under urgent medical supervision. Patients weaned off oral steroids whose adrenocortical function is still impaired should carry a steroid warning card indicating that they may need supplementary systemic steroid during periods of stress, e.g. worsening asthma attacks, chest infections, major intercurrent illness, surgery, trauma, etc. Inhaled therapy may unmask underlying eosinophilic conditions (e.g. Churg Strauss syndrome). These cases have usually been associated with reduction or withdrawal of oral corticosteroid therapy. Similarly replacement of systemic steroid treatment with inhaled therapy may unmask allergies such as allergic rhinitis or eczema previously controlled by the systemic drug. These allergies should be symptomatically treated with antihistamine and/or topical preparations, including topical steroids. Patients in a medical or surgical emergency, who require high doses of inhaled steroids and/or intermittent treatment with oral steroids, are at risk of impaired adrenal reserve. The extent of the adrenal impairment may require specialist advice before elective procedures. The possibility of residual impaired adrenal response and elective situations likely to produce stress and appropriate corticosteroid treatment must be considered. Lack of response or severe exacerbations of asthma should be treated by increasing the dose of inhaled fluticasone propionate or by giving a systemic steroid and/or an antibiotic if there is an infection. Special care is necessary in patients with active or quiescent pulmonary tuberculosis. Patients on corticosteroid therapy may have adrenocortical suppression. **MANAGEMENT OF OVERDOSAGE:** Monitoring of adrenal reserve may be indicated. Treatment with inhaled fluticasone propionate should be continued at a dose sufficient to control asthma. **APPLICANT:** GlaxoSmithKline South Africa (Pty) Ltd; (Co. reg. no.1948/030135/07). 39 Hawkins Avenue, Epping Industria 1, Cape Town, 7460.

Reference: 1. Laube BL, Janssens HM, de Jongh FHC, *et al*. What the pulmonary specialist should know about the new inhalation therapies. *Eur Respir J* 2011;**37**:1308-1331. **2.** VORTEX® package insert.

For full prescribing information, please refer to the package inserts approved by the Medicines Regulatory Authority.
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