Late Breaking Clinical Trial: A Dose Finding Study Of The Oral Direct Factor XA Inhibitor Apixaban in the Treatment of Patients with Acute Symptomatic Deep Vein Thrombosis - The Botticelli Investigators

Buller, H.R.
Department of Vascular Medicine, Academic Medical Center, Amsterdam, Netherlands
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INTRODUCTION

Apixaban is a new, direct-acting inhibitor of coagulation Factor Xa. It binds to the active site of Factor Xa without requiring anti-thrombin.

The efficacy and safety of this compound was evaluated in patients with confirmed deep vein thrombosis (DVT).

METHODS

Patients were allocated randomly to 1 of 3 double-blind regimens of apixaban (5 mg BID,10 mg BID, or 20 mg QD), or conventional treatment with low molecular weight heparin or fondaparinux followed by open-label vitamin K antagonist (VKA) (dose adjusted to an INR 2.0-3.0). Treatment continued for 84-91 days. A bilateral venous compression ultrasound (CUS) of the legs and a perfusion lung scan (PLS) were obtained within 36 hours from randomization and at 12 weeks.

The primary efficacy outcome was the composite of symptomatic recurrent venous thromboembolism (VTE) and deterioration of the thrombotic burden as assessed by repeat bilateral CUS and PLS. The principal safety outcome was the composite of major and clinically relevant non-major bleeding. All outcomes were evaluated by a central, independent and blinded, adjudication committee (CIAC).

RESULTS

A total of 520 patients were randomized. For apixaban 5 mg BID, 10 mg BID, 20 mg QD, and for VKA, the primary efficacy outcome rates were 6.0%, 5.6%, 2.6%, and 4.2%, respectively, and the principal safety outcome rates were 8.6%, 4.5%, 7.3%, and 7.9%, respectively.

The rates of symptomatic VTE were 2.6%, 3.2%, 1.7%, and 2.5%, respectively, and the rates of major bleeding were 0.8%, 0, 0.8%, and 0, respectively.

CONCLUSION

This oral direct factor Xa inhibitor that can be given as the sole treatment in a fixed dose appears to be a very attractive alternative to standard therapy in patients with DVT.

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