MedicalXpress

Hokusai-VTE study suggests certain sub-groups of venous thromboembolism patients may need review

September 1 2013

In the treatment of venous thromboembolism (VTE), the oral anticoagulant edoxaban resulted in equal efficacy and better safety compared to standard warfarin when either drug was used with initial low molecular weight heparin (LMWH), according to the results of the Hokusai-VTE trial.

In the landscape of new trials with oral anticoagulants, the Hokusai-VTE findings offer fresh insight into a previously under-represented subgroup of patients with pulmonary embolism (PE), suggesting that treatment for this group might need to be different than for other VTE patients, said lead investigator Harry R. Büller, MD, who presented the findings here at the European Society of Cardiology Congress.

"I think our findings are going to shake things up a little bit," said Dr. Büller, from the Department of Vascular Medicine at Academic Medical Center in Amsterdam.

"What makes this study unique is new insight that there are subgroups in which we might need to revisit what we currently think about the treatment of VTE."

The Hokusai-VTE trial included a broader spectrum of VTE patients compared to those included in other recent oral anticoagulant trials, including a large subgroup (30%) of patients with PE and right

ventricular dysfunction, and another subgroup (20%) at high risk for bleeding due to renal impairment and low body weight.

In total, 4921 patients with deep-vein thrombosis and 3319 with pulmonary embolism received initial subcutaneous LMWH therapy and were then randomized to receive either 60 mg of edoxaban daily (30 mg for those at higher risk for bleeding, ie., creatinine clearance 30-50 mL/min or body weight below 60 kg), or warfarin (per standard of care) for 3 to 12 months.

For the primary efficacy endpoint of recurrent symptomatic venous thromboembolism, the study found that edoxaban was non-inferior to warfarin , with the primary endpoint of recurrent symptomatic VTE occurring in 3.2% vs 3.5% respectively (P