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ATLAS ACS 2 Trial Reports on Low Dose Rivaroxaban

The lower of the two doses of the new oral anticoagulant rivaroxaban (Xarelto, Bayer/Johnson & Johnson) tested in the ATLAS ACS 2 TIMI 51 trial has shown promising results, with a reduction in overall and cardiovascular mortality vs placebo, despite an increased risk of bleeding and intracranial haemorrhage (ICH).

The trial, presented at the AHA 2011 Scientific Sessions today compared two doses of rivaroxaban with placebo in ACS patients. All patients were taking low-dose (75-100 mg) aspirin and 93% were also on clopidogrel (Plavix, Bristol-Myers Squibb/Sanofi-Aventis). Study treatment was started an average of 4.6 days after the ACS event. Patients with a previous stroke or transient ischemic attack (TIA) were excluded, as this group has been shown to have a particularly high risk of ICH in previous trials of other antithrombotic agents. The population was high risk, with half having had a STEMI.

Both rivaroxaban doses reduced the primary end point of cardiovascular death/MI/stroke, at the cost of increased bleeding rates. The 2.5-mg twice-daily dose had the better benefit/risk balance, due to a lower bleeding risk than the 5-mg twice-daily dose.

"Thus, the addition of very low-dose anticoagulation with rivaroxaban may represent a new treatment strategy in patients with a recent acute coronary syndrome," the ATLAS investigators conclude in the New England Journal of Medicine paper, published online today to coincide with the AHA presentation.

The trial randomized 15 526 ACS patients to one of the two doses of rivaroxaban or placebo for a mean of 13 months and up to 31 months.

The overall results showed a significant 16% reduction in the primary efficacy end point for the two doses combined vs placebo, with a threefold increase in major bleeding and intracranial hemorrhage but no significant increase in fatal bleeding.

Published on : Mon, 14 Nov 2011