MÆDICA - a Journal of Clinical Medicine

JOURNAL CLUB

Rivaroxaban Better than Enoxaparin for Extended Thromboprophylaxis after Hip Arthroplasty

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Extended thromboprophylaxis for 5 weeks after total hip arthroplasty significantly reduces the occurrence of venous thromboembolic events, as compared to short-term thromboprophylaxis. The current options are rather limited. Low-molecular-weight heparin is expensive and sometimes difficult to administer to some of the patients. Oral anticoagulants, such as vitamin K antagonists, are difficult to manage, especially because of the need of frequent monitoring, for safety reasons.

Rivaroxaban is an oral direct inhibitor of factor Xa, with a bioavailability of 80%. The study RECORD 1 (Regulation of Coagulation in Orthopedic Surgery to Prevent Deep Venous Thrombosis and Pulmonary Embolism 1) compared its efficacy and safety to those of enoxaparin, for extended thromboprophylaxis in patients undergoing total hip arthroplasty.

4541 patients were randomized either to once-daily oral10 mg of rivaroxaban (6-8 hours after wound closure) or subcutaneous 40 mg enoxaparin (12 hours before surgery and 6-8 hours after wound closure). All the patients also received placebo tablets or injections. After the study termination, at day 36, all the patients underwent bilateral venography, and some of them continued the thromboprophylaxis when needed (but not with study drug). The primary efficacy outcome was the composite of deep-vein thrombosis, nonfatal pulmonary embolism, or death from any cause at 36 days. The main secondary efficacy outcome was major venous thromboembolism (proximal deep-vein thrombosis, nonfatal pulmonary embolism, or death from venous thromboembolism). The primary safety outcome was major bleeding.

A total of 3029 patients were included in the per-protocol population, and 3153 were included in the modified intention-to-treat population. Deep-vein thrombosis occurred in 18 of 1595 patients (1.1%) in the rivaroxaban group and in 58 of 1558 patients (3.7%) in the enoxaparin group (absolute risk reduction, 2.6%; 95% [CI], 1.5 to 3.7; $P<0.001$). 4 out of 1686 patients had major venous thromboembolic events (0.2%) in the rivaroxaban group and 33 out of 1678 patients (2.0%) in the enoxaparin group (absolute risk reduction, 1.7%; 95% CI, 1.0 to 2.5; $P<0.001$). As far as safety profile is concerned, there were no statistically significant differences between the 2 groups: 6 major bleeding out of 2209 patients (0.3%) in the rivaroxaban group, and 2 out of 2224 patients (0.1%) in the enoxaparin group ($P=0.18$).

In this randomized double-blind study, evidence suggested that 10 mg per day of oral rivaroxaban is more effective than 40 mg per day of subcutaneous enoxaparin in preventing venous thromboembolic events, in patients undergoing total hip arthroplasty, with a similar safety profile.

Comment on the paper:
Eriksson BI, Borris LC, Friedman RJ et al – Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty. *N Engl J Med* 2008 June 26; 358:2765-2775