ANTICOAGULATION THERAPY

Assessment of extended-duration enoxaparin for VTE

In the randomized, placebo-controlled EXCLAIM trial, Russell Hull and colleagues evaluated the efficacy and safety of extended-duration enoxaparin (low-molecular-weight heparin). A large proportion of hospitalized patients are at risk of venous thromboembolism (VTE) and should receive appropriate prophylaxis. The optimal duration of therapy is not known, but the investigators of this study hypothesized that a 4-week enoxaparin regimen would be beneficial for acutely ill medical patients with reduced mobility.

Enrolled patients initially received open-label enoxaparin for 10 ± 4 days and were then randomly assigned to receive 40 mg per day of enoxaparin ($n = 2,975$) or placebo ($n = 2,988$) for an additional 28 ± 4 days. The primary efficacy end point was VTE—defined as the composite of symptomatic or asymptomatic proximal deep-vein thrombosis, symptomatic pulmonary embolism, or

fatal pulmonary embolism during the treatment period.

Extended-duration enoxaparin significantly reduced the incidence of VTE compared with placebo at the end of the intervention period (2.5% and 4%, respectively); this effect was unchanged at 90 days. However, the number of major hemorrhages at 30 days was significantly greater in the extended-duration enoxaparin group than the placebo group (25 and 10 events, respectively). The eligibility criteria were amended during the study, leading to the inclusion of patients at even greater risk of VTE. Therefore, the findings cannot be generalized to the whole patient population.

The benefits of extended-duration enoxaparin seemed to be restricted to patients aged >75 years, women, and those with level 1 immobility (those requiring total bed rest or being sedentary without bathroom privileges). Findings from

this study suggest a favorable benefit-to-risk ratio for this group of patients, but extended-duration enoxaparin cannot be recommended for patients who are not at high risk of VTE. “Decisions about the use of prophylaxis should depend on individual patient characteristics, preferences, and values,” write the investigators.

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Original article Hull, R. D. *et al.* Extended-duration venous thromboembolism prophylaxis in acutely ill medical patients with recently reduced mortality: a randomized trial. *Ann. Intern. Med.* 153, 8–18 (2010)