

Dabigatran etexilate shows at least similar effect compared with enoxaparin in prevention of embolic thromboembolism following total hip arthroplasty

(RENOVATE 2 trial)

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Dabigatran etexilate is a new anticoagulant which has demonstrated as efficient after deep vein thrombosis and atrial fibrillation. In these situation the benefit came from a better anticoagulation with a lower incidence of thrombotic events and with a much lower incidence of non-haemorrhagic strokes compared with warfarin. The purpose of this randomized trial was to demonstrate non-inferiority of 220 mg oral dabigatran etexilate compared to 40 mg subcutaneous enoxaparin administered once daily in terms of safety and efficacy administered in the first day after hip surgery. The primary efficacy end-point was a composite of total venous thromboembolic events and all cause mortality during the treatment period. Safety endpoints include major bleeding events, clinically relevant bleeding events, any bleeding events.

The trial has been stopped prematurely by the ethics committee.

Patients were randomized to either oral dabigatran 220 mg once daily (n=1010) or 40 mg subcutaneous enoxaparin (n=1003) for an

average of 32 days after total hip replacement.

Dabigatran was found to be as effective and safe as injected enoxaparin with respect to the trial's primary end point of total VTE and all-cause mortality (7.7% vs. 8.8% of patients, respectively with a noninferiority margin statistically significant, $p < 0.0001$). The most important finding relates to major VTE and VTE-related death. The difference was 2.2% vs 4.2% in the dabigatran vs enoxaparin groups, respectively, again statistically significant.

Major bleeding events—classified as fatal, in a critical organ, or associated with a 20-mg/L fall in hemoglobin in excess of expected levels—were comparable between both treatment groups, 1.4% of patients in the dabigatran group vs 0.9% of those receiving enoxaparin had episodes of major bleeding ($p = 0.40$).

The study opens an opportunity in which the new generation of oral anticoagulant therapy can replace not only old and non predictable oral anticoagulation with warfarine, but also subcutaneous anticoagulation, with similar efficiency, similar bleeding risks and for sure lower costs. \square

Comment on a paper:

Huo M. et al – RE-NOVATE 2: Dabigatran noninferior to enoxaparin for VTE-event prophylaxis in setting of hip surgery, report at the European Congress of Hematology Association, 15.jun.2010