Policy Changing Paper

PREVENT CLOT (Aspirin Versus Low-Molecular-Weight Heparin for Thromboprophylaxis): A Randomized Clinical Trial of Over 12,000 Orthopaedic Trauma Patients

METRC; ***Robert V. O'Toole, MD***
21 Trauma Centers, Baltimore, Maryland, UNITED STATES

Purpose: Current clinical guidelines recommend low-molecular-weight heparin for thromboprophylaxis in patients with a fracture, but trials comparing its effectiveness against aspirin are lacking. This multicenter pragmatic randomized clinical trial aimed to determine if aspirin was noninferior to low-molecular-weight heparin for thromboprophylaxis in orthopaedic trauma patients.

Methods: We performed a randomized clinical trial involving patients with an operatively treated extremity fracture or any pelvis or acetabular fracture regardless of treatment. Patients were recruited from 21 academic trauma centers in the United States and Canada. We randomly assigned consenting patients in a 1:1 ratio to receive a twice-daily administration of low-molecular-weight heparin (30 mg enoxaparin) or a twice-daily administration of 81 mg aspirin. The primary outcome was all-cause mortality by 90 days after randomization. Secondary outcomes included cause-specific death, non-fatal pulmonary embolism, deep vein thrombosis, bleeding complications, wound healing complications, and infection 90 days after randomization. The primary analysis will use treatment-specific Kaplan-Meier and cumulative incidence function estimators with an intention-to-treat approach.

Results: As of January 31, 2022, the trial has enrolled 12,216 patients (mean age, 45 years [standard deviation (SD), 18]; 62% male) with 95% follow-up at 90 days on the primary outcome. The final analysis of our primary and secondary outcomes will be presented at the 2022 OTA Annual Meeting.

Conclusion: The results of the PREVENT CLOT study will inform whether orthopaedic trauma providers and patients should consider aspirin as a suitable thromboprophylaxis substitute for low-molecular-weight heparin in fracture patients. The study question required the performance of the largest treatment trial to date in our field, with over 12,000 patients enrolled. Our methodology and high follow-up rate should provide compelling evidence to resolve this important clinical question.