

Inpatient Compliance with Venous Thromboembolism Prophylaxis in Orthopaedic Trauma: A Pragmatic Randomized Controlled Trial of Aspirin Versus Low Molecular Weight Heparin

Bryce Haac, MD; Richard Van Besien, BA; Nathan N. O'Hara¹; Gerard P. Slobogean, MD¹; Deborah Stein, MD, MPH; Robert V. O'Toole, MD; Theodore T. Manson, MD

¹R Adams Cowley Shock Trauma Center, University of Maryland, Baltimore, Maryland, USA

Purpose: It is unknown if aspirin (acetylsalicylic acid [ASA]) or enoxaparin (low molecular weight heparin [LMWH]) is the more efficacious venous thromboembolism (VTE) prophylaxis after orthopaedic trauma. Missed doses are associated with increased VTE, and patient refusal is a common reason for missed doses. We sought to compare inpatient compliance with these 2 regimens and identify risk factors for noncompliance.

Methods: We conducted a pragmatic randomized controlled trial of adults presenting to a Level I trauma center with an operative extremity fracture proximal to the tarsals/carpals or any pelvic or acetabular fracture requiring VTE prophylaxis. Patients were randomized to receive either LMWH 30 mg BID or ASA 81 mg BID for the duration of indicated prophylaxis. Our primary outcome measure was the percentage of doses received compared to the ideal number of doses. Of 483 patients who met study exclusion/inclusion criteria, 329 patients (68.1%) consented to enroll in the IRB-approved study: 165 randomized to ASA and 164 to LMWH.

Results: There was no difference in percentage of patients who missed a dose (ASA: 41.2% vs LMWH: 43.3%, $P = 0.7$) or mean number of missed doses (0.6 vs 0.7 doses, $P = 0.4$) between arms. The majority of patients (57.8%, $n = 190$) did not miss any doses. Only 6.4% ($n = 21$) of patients had their assigned prophylaxis stopped with no significant difference between arms ($P = 0.1$). Reasons for missed doses and refusal rates were similar, except only patients in the aspirin arm missed doses due to inability for enteral medication administration (10.3% vs 0%, $P < 0.01$). Patients with upper extremity injuries (odds ratio [OR]: 1.99; 95% confidence interval [CI]: 1.20-3.30; $P = 0.01$) were more likely to miss a dose. Finally, 10.6% of patients ($n = 35$) received at least 1 dose of the non-assigned prophylaxis regimen postrandomization without a medical indication but there was no significant difference in rates between treatment arms ($P = 0.6$).

Conclusion: Inpatient adherence was similar for ASA and LMWH. Missed doses were most often associated with an operative procedure; however, patient refusal and inability to give enteric medications also contributed. Interestingly, compliance rates varied with fracture patterns. These data should help reassure clinicians that these medicines have similar inpatient compliance and prove crucial to investigators designing larger trials to explore efficacy of these medicines.