A Prospective Randomized Controlled Trial Comparing Subcutaneous Enoxaparin and Oral Rivaroxaban for Venous Thromboembolism Prophylaxis in Orthopaedic Trauma Patients

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Purpose: Venous thromboembolism (VTE) is a potential complication following orthopaedic trauma surgery. There is no standard for orthopaedic trauma patient VTE chemoprophylaxis. New oral anticoagulants (NOACs) have emerged as an effective, safe, and potentially less cumbersome alternative to subcutaneous injectable low molecular weight heparin (LMWH). NOACs, like LMWHs, have proven efficacy in preventing VTE. The purpose of our study was to compare VTE chemoprophylaxis with oral NOACs (rivaroxaban) versus injectable LMWH (enoxaparin) upon discharge home from the hospital.

Methods: We conducted a prospective randomized controlled trial of orthopaedic trauma patients at a single Level I trauma center. Inclusion criteria were adult patients (>18 years) with fractures requiring VTE prophylaxis based on service protocols upon discharge home from the hospital. Those who were discharged home on aspirin or without VTE prophylaxis, discharged to post-acute care facilities, non-English speakers (for validated surveys), pregnant or institutionalized individuals, and those on chronic anticoagulation were excluded. Patients were randomized to a 20-day course of subcutaneous injectable enoxaparin (Group A) or oral rivaroxaban (Group B). Primary outcomes were measured using validated survey tools, the Treatment Satisfaction Questionnaire for Medication (TSQM-9) and the Morisky Medication Adherence Scale (MMAS-8). Secondary outcomes included patient monitoring for VTE, major bleeding events, or adverse medication reactions. Data were obtained at 2, 6, and 12 weeks post discharge.

Results: Preliminary data includes 110 randomized patients (Group A = 58; Group B = 52) with no significant difference in demographic or injury characteristics. Patients had statistically significant higher medication satisfaction, confidence, ease of use, and convenience scores across all 9 items on the TSQM-9 (P values: <0.001 to 0.02). Group A had more overall low-compliance patients, but there was no significant difference overall based on the MMAS-8 ($P = 0.65$). No patients in either group suffered a diagnosed VTE or major bleeding event. Group A reported more adverse events, including injection site bruising and inability to self-administer their medication (22%). Group B experienced no reportable adverse events. For uninsured patients paying out of pocket, Group A medication costs were $40, and Group B costs were $4.

Conclusion: Patients were more satisfied using oral compared to injectable postoperative VTE prophylaxis following discharge after orthopaedic trauma surgery. While medication compliance, VTE, or bleeding events were not significantly different between subcutaneous injectables and oral medications, there were more adverse reactions and higher costs for the injectable group.