A Randomized Controlled Trial of Oral and IV Tranexamic Acid: The Same Efficacy at Lower Cost?

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Introduction: Tranexamic acid (TXA) is a synthetic antifibrinolytic agent successfully used intravenously (IV) to reduce blood loss following total knee arthroplasty (TKA). An oral formulation of the medication is available, at a fraction of the cost of the IV preparation. The purpose of this randomized controlled trial is to determine if oral TXA is equivalent to IV TXA in reducing blood loss in TKA.

Methods: In this double-blinded, placebo-controlled trial, 73 patients undergoing primary TKA were randomized to receive 1.95g of TXA orally two hours preoperatively or a 1g IV bolus prior to wound closure. The primary outcome was reduction of hemoglobin. Power analysis determined that 30 patients were required in each group to identify a 1.0g/dL difference between groups with an alpha of 0.05 and a beta of 0.90. Equivalence analysis was performed with pooled and Satterthwaite t-tests with a p-value of < 0.05 suggesting equivalence between treatments.

Results: 36 Patients received IV TXA, 32 oral and 5 were excluded for protocol deviations. Patient demographics were similar between groups suggesting successful randomization. There was no difference in the mean reduction of hemoglobin between the oral and IV groups (3.45g/dL vs 3.31g/dL respectively; $p<0.001$, equivalence). Similarly, total blood loss was equivalent for oral and IV administrations at 1267ml vs 1229ml respectively ($p=0.007$, equivalence). One patient in each treatment group was transfused, and no patients experienced a thromboembolic event.

Conclusions: Oral TXA provides equivalent reductions in blood loss in the setting of primary TKA, at a cost of $14 compared to $47 to $108 depending on the IV formulation selected. As approximately 700,000 primary TKA are performed in the United States annually, a switch to oral TXA could yield total cost savings of between $23 million and $67 million dollars per year for our health care system.