Paper #34

A Multi-Center Randomized Clinical Trial of Tranexamic Acid in Revision Total Hip Arthroplasty: Does the Dosing Regimen Matter? ◊

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Introduction: The purpose of this multicenter, randomized clinical trial was to determine the optimal dosing regimen of tranexamic acid (TXA) to minimize perioperative blood loss for revision total hip arthroplasty (THA).

Methods: Six centers prospectively randomized 170 revisions to one of four regimens: 1) 1g of intravenous (IV) TXA prior to incision, 2) a double dose regimen of 1g IV TXA prior to incision and 1g IV TXA during wound closure, 3) a combination of 1g IV TXA prior to incision and 1g intraoperative topical TXA, or 4) three doses of 1950mg oral TXA administered 2 hours preoperatively, 6 hours postoperatively, and on the morning of postoperative day one. Randomization was based upon revision subgroups to ensure equivalent group distribution, including femur only, acetabulum only, both component, explant/spacer, and second stage reimplantation. Patients undergoing an isolated modular exchange were excluded. An a priori power analysis (alpha=0.05; beta=0.80) determined 40 patients per group were required to identify a 1g/dL difference in postoperative hemoglobin reduction between groups. Per-protocol analysis involved an analysis of variance, Fisher's exact tests, and two one-sided t-tests for equivalence.

Results: Demographic and surgical variables were equivalent between groups. No significant differences were found between TXA regimens when evaluating reduction in hemoglobin (single IV=3.4 g/dL, double IV=3.5 g/dL, combined=3.5 g/dL, oral=3.5 g/dL; p=0.93), calculated blood loss (p=0.90), or transfusion rates (single IV=14%, double IV=18%, combined=16%, oral=18%; p=0.97). Equivalence testing revealed all possible pairings were statistically equivalent, assuming greater than a 1g/dL difference in hemoglobin reduction as clinically relevant.

Conclusions: All TXA regimens tested had equivalent blood-sparing properties in the setting of revision THA. Surgeons should consider the lowest effective dose and the most economical regimen.

◊ The FDA has not approved tranexamic acid for use in orthopaedics.