

Low versus High Dose Tranexamic Acid in Adult Spinal Deformity Surgery: A Randomized, Controlled Trial

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Statistical Analysis Plan

Parametric data were expressed as mean \pm standard deviation and compared using the Student t test and Chi-square. Nonparametric data were expressed as median (interquartile range) and compared via the Mann-Whitney U test. Prior to analysis, outlier values were examined to determine their origin and ensure they did not represent data entry errors. Enrollment and surgical data were compared to ensure successful randomization. Data were analyzed on an intention-to-treat basis. Only patients who enrolled and underwent surgery were considered completed. Randomization failures were patients who enrolled but failed to undergo surgery as scheduled and were not randomized. Mean EBL was the primary outcome measure, while number of PRBC transfused, mean number of intraoperative complications and 90-day complications were secondary outcomes. All tests were 2 sided and were considered statistically significant if the P value was less than 0.05. Statistical analysis was performed using JMP, version 13 (SAS Institute Inc., Cary, North Carolina, USA).