DOES THROMBIN DOSE MATTER FOR INTRA-OPERATIVE HEMOSTASIS? A RETROSPECTIVE CASE-CONTROLLED STUDY

Barry Stevenson, PharmD1; Joshua D. Steelman, PharmD1; Lisa Hall Zimmerman, PharmD1; Zachary Bullard, PharmD1; Lesly Jurado, PharmD1; George Alsina, MD2; Renee Wall, PA-C3

New Hanover Regional Medical Center; Wilmington, NC
1. Department of pharmacy
2. Department of neurosurgery
3. Department of orthopedics

Purpose:
Thrombin, a hemostatic agent, is often employed due to its ability to convert endogenous fibrinogen into fibrin. Limited data exists regarding thrombin doses and concentrations to optimize hemostasis. Hence, the purpose of this study was to compare thrombin dosing strategies to determine effectiveness and safety in providing hemostasis intra-operatively.

Methods:
This retrospective study evaluated patients, age ≥ 18 years, who underwent a neurosurgical or orthopedic spine procedure and received thrombin intra-operatively. Operational change of thrombin 20,000 unit vials to 5,000 unit vials occurred in October 2014 and patients were compared before and after the conversion. Patients were case matched in a 1:1 ratio based on surgeon and surgical procedure. Patients were stratified by thrombin dose defined as <20,000 (T<20K) versus ≥20,000 (T≥20K) units. Effectiveness of thrombin for hemostasis was measured by identifying total blood loss during surgery, blood products administered, and hemoglobin trends for 72 hours after the end of surgery time. Safety was measured by identifying adverse drug reactions including venous thromboembolism, acute coronary syndrome, cerebral vascular accident, or anaphylaxis. A cost analysis was also performed. SPSS v21.0 was used for the appropriate statistical analysis and a p-value < 0.05 was considered significant.

Results:
Of the 536 evaluated, 112 patients were matched (56 T<20K vs 56 T≥20K) with mean age of 59±14 (T<20K) vs 56±13 (T≥20K). The most common surgical procedures performed were discectomies and fusions accounting for 49.1% of cases. Overall, thrombin dose was different between groups. 13392±7077 T<20K vs 27500±11793 T≥20K, units, p=<0.001. No differences were found regarding effectiveness with estimated blood loss of 128±142 T<20K vs 171±298 T≥20K, ml, p=0.35. Safety was
not different between groups for adverse events. Procedure time was similar between groups, 153±54 T<20K vs 163±60 T≥20K, minutes, p=0.35. The median [IRQ] number of vials used between the groups was different, 2 [2,4] T<20K (5000 unit vials) vs 1[1,2] T≥20K (20000 unit vials), p<0.001. The cost analysis between the two groups showed approximately a $230,000 potential yearly savings after conversion to the 5000 unit vial.

Conclusion:
Thrombin plays a vital role in hemostasis during neurosurgical and orthopedic spine procedures. We identified that converting from a 20000 unit to a 5000 unit vial had no alteration to thrombin’s effectiveness and safety when comparing ≥20,000 and <20,000 units. The true benefit from this study came from the estimated cost savings identified from switching to a smaller vial size without losing effectiveness.