Prehospital TXA for Severe Trauma (PATCH) Trial

2024 THOR CONFERENCE

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Disclosures

Decisio Health	Founder and BoD
Zibrio	BoD
QinFlow	BoD
CCJ Medical	BoD
WFIRM	Consultant
Aspen Medical	Consultant
Co-Inventor of the JETT	Royalty from UT

DoD, NIH, DARPA and CSL Grants

Prehospital Tranexamic Acid for Severe Trauma

NEJM 2023

The PATCH-Trauma Investigators and the ANZICS Clinical Trials Group*

From July 28, 2014, to September 28, 2021, 1310 patients were enrolled and treated by 15 emergency medical services and at 21 hospitals in Australia, New Zealand, and Germany.

Randomized and blinded

Adults with major trauma and suspected trauma-induced coagulopathy who were being treated in advanced trauma systems, prehospital administration of 1 gram of TXA followed by an infusion of 1 gram over 8 hours.

Primary outcome was functional status at 6 months (GOS-E)

Prehospital assessment of coagulopathy risk was performed with the use of the Coagulopathy of Severe Trauma (COAST) score.

COAST scores range from 0 to 7,
with 1 point assigned for each of the following variables:
entrapment in a vehicle, SBP < 100 mm Hg,
temperature of < 35C,
suspected pneumothorax, and
suspected intraabdominal or pelvic injury.
Additional points are assigned if the SBP < 90 mm Hg or
if the temperature is < 32C.
Patients with a COAST score of 3 or greater are
considered to be at high risk for coagulopathy.

A total of 24.1% of the patients subsequently had laboratory evidence of early coagulopathy

Results

TXA did not result in a greater number of patients surviving with a favorable functional outcome at 6 months than placebo (both 53%)

PATCH Mortality Results

By 24 hours after injury, 64 of 657 patients (9.7%) in the TXA group and 90 of 640 patients (14.1%) in the placebo group had died.

By 28 days, 113 of 653 patients (17.3%) in the TXA group and 139 of 637 (21.8%) in the placebo group had died.

By 6 months, 123 of 648 patients (19.0%) in the TXA group and 144 of 629 (22.9%) in the placebo group had died.

Other Results

Inpatients were screened for DVTs in the legs with the use of Doppler ultrasonography on or around day 7.

The number of serious adverse events, including vascular occlusive events, did not differ between the groups.

Issues

Primary outcome data were missing for 13% of the patients, mostly because of loss to follow-up.

Protocol deviations occurred in 215 patients (32.7%) in the tranexamic acid group and in 238 patients (37.0%) in the placebo group,

Including 104 (15.8%) and 106 (16.5%), respectively, who received open-label tranexamic acid in the hospital

Other more recent data suggest a higher dose may have a beneficial effect

JAMA | Original Investigation

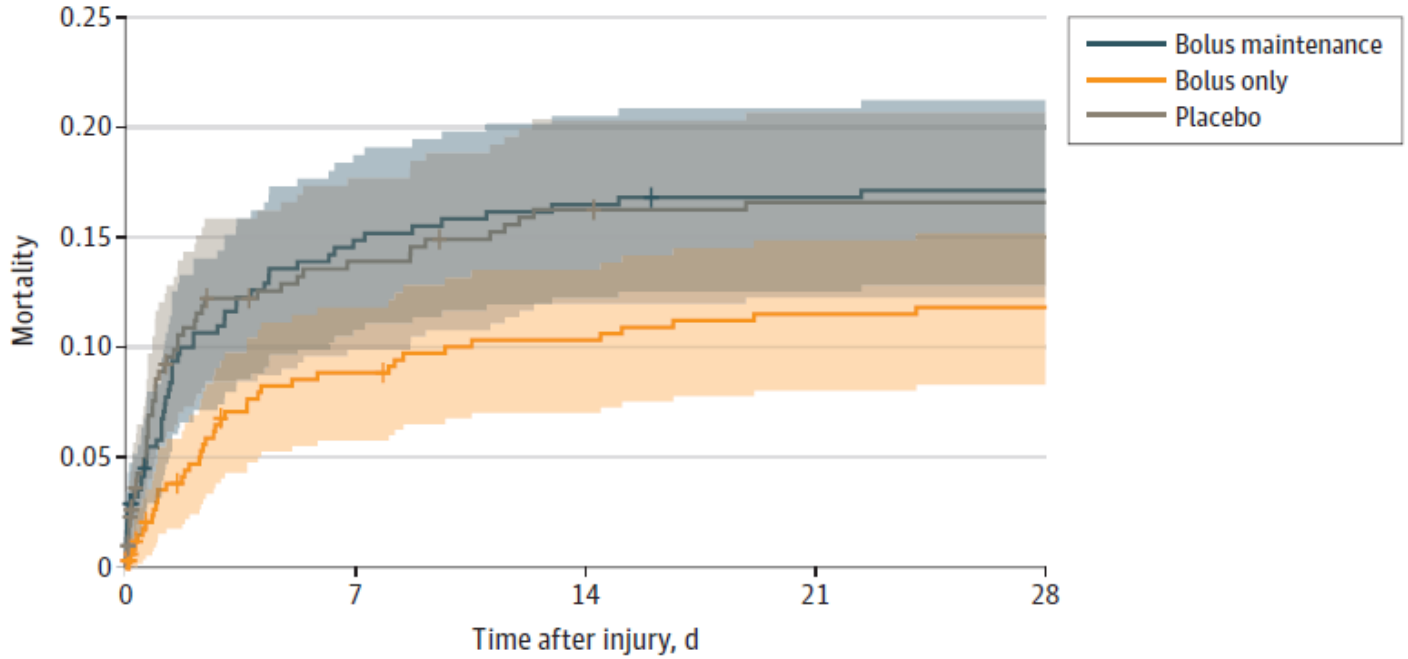
Effect of Out-of-Hospital Tranexamic Acid vs Placebo on 6-Month Functional Neurologic Outcomes in Patients With Moderate or Severe Traumatic Brain Injury

Rowell S et al, JAMA, 2020

20 trauma centers and 39 EMS agencies in US and Canada
N = 1280, prehospital intervention
Isolated TBI ≥ 15 years, GCS ≤12, and SBP ≥ 90mmHg
3 TXA groups
1 + 1, 2 + 0, 0 + 0
No safety issues
No diff in LY30 on admission TEGs
No difference in the primary outcome of GOSE at 6 months

545/966 (56%) had a positive CT scan
In these patients very significant outcome differences in 28 day mortality
GOSE 6 month no diff but DRS was significantly improved

Figure 2. Post Hoc Descriptive Analysis of Mortality Through 28 Days in a Study of the Effect of Tranexamic Acid vs Placebo on Neurologic Outcomes in Patients With Traumatic Brain Injury



Among 56% of patients with an ICH, 28- day mortality was

18% in the 2 and 1 gram group

26% in the 1 and 1 gram group

27% in the placebo group

My conclusions

No diff in functional outcomes at 6 months, but outcome data were missing for 13%

Mortality diff of 3-4% that showed up early and persisted.

16% in both groups used TXA in the hospital

No thrombosis issues, with the studied dose and they looked

But used a dose that doesn’t make sense to me

Tranexamic Acid During Radical Cystectomy

JAMA Surg Oct 2024

A Randomized Clinical Trial

Rodney H. Breau, MSc, MD[1]; Luke T. Lavallée, MSc, MD[1]; Ilias Cagiannos, MD[2]; et al

Conclusions and relevance: Results of this randomized clinical trial reveal that TXA did not reduce blood transfusion in patients undergoing open radical cystectomy for bladder cancer. Based on this trial, routine use of TXA during open radical cystectomy is not recommended.

Tranexamic Acid in Patients Undergoing Liver Resection

JAMA Aug 2024

The HeLiX Randomized Clinical Trial

Paul J. Karanicolas, MD, PhD[1,2,3]; Yulia Lin, MD[4,5]; Stuart A. McCluskey, MD, PhD[6,7]; et al

Conclusions and relevance: Among patients undergoing liver resection for a cancer-related indication, tranexamic acid did not reduce bleeding or blood transfusion but increased perioperative complications.

Thank You!

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