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Current Practices in Tranexamic Acid Administration for Pediatric Trauma Patients in the United States

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ABSTRACT

Background: Although controversial, early administration of tranexamic acid (TXA) has been shown to reduce mortality in adult patients with major trauma. Tranexamic acid has also been successfully used in elective pediatric surgery, with significant reduction in blood loss and transfusion requirements. There are limited data to guide its use in pediatric trauma patients. We sought to determine the current practices for TXA administration in pediatric trauma patients in the United States.

Methods: A survey was conducted of all the American College of Surgeons-verified Level I and II trauma centers in the United States. The survey data underwent quantitative analysis.

Results: Of the 363 Level I and II qualifying centers, we received responses from 220 for an overall response rate of 61%. Eighty of 99 verified pediatric trauma centers responded for a pediatric trauma center response rate of 81%. Of all responding centers, 148 (67%) reported they care for pediatric trauma patients, with an average of 513 pediatric trauma patients annually. The pediatric trauma centers report caring for an average of 650 pediatric trauma patients annually. Of all centers caring for pediatric trauma, 52 (35%) report using TXA, with the most common initial dosing being 15 mg/kg (68%). A follow-up infusion was utilized by 45 (87%) of the programs, most commonly dosed at 2 mg/kg/hr × 8 hr utilized by 24 centers (54%).

Conclusion: Although the clinical evidence for TXA in pediatric trauma patients is limited, we believe that consideration should be given for use in major trauma with hemodynamic instability or significant risk for ongoing hemorrhage. If available, resuscitation should be guided by thromboelastography to identify candidates who would most benefit from antithrombolytic administration. This represents a low-cost/low-risk and high-yield therapy for pediatric trauma patients.

Key Words

Coagulopathy, Hemorrhage, Pediatric, Tranexamic acid, Trauma

Hemorrhage in trauma accounts for 30%–40% of trauma deaths in the United States each year. It is considered the most preventable cause of mortality and morbidity following traumatic brain injury (Kauvar, Lefering, & Wade, 2006). In addition, 25% of these events are characterized by a coagulopathy caused by depletion of clotting factors, decreased platelets, and an increase in fibrinolysis (Ramirez, Spinella, & Bochicchio, 2017). It has been recognized that coagulation defects are responsible for disproportionate mortality concerning hemorrhage, bringing tranexamic acid (TXA) into the spotlight (Dzik et al., 2011).

Tranexamic acid is a lysine analog that blocks the conversion of plasminogen to plasmin through competitive inhibition of the serine protease in plasmin, thereby decreasing fibrin clot breakdown and decreasing bleeding (Hunt, 2015). The 2010 CRASH-2 study showed that TXA administration reduced death in trauma victims older than 16 years (Beno, Ackery, Callum, & Rizoli, 2014). A Cochrane review found that TXA use resulted in a 10% decrease in trauma-related mortality in patients of all ages. Hemorrhage is the most common cause of death in solid-organ injuries and blunt thoracoabdominal trauma in children. As a result, hemorrhage is the second leading cause of traumatic death in children (Whittaker et al., 2013) after traumatic brain injury. Despite limited research or data on TXA administration in the pediatric population, children of all ages respond consistently in coagulation response to tissue injury (Beno et al., 2014). Thus, it may be considered reasonable to administer TXA following injury. Recently, a retrospective cohort study in Afghanistan

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found that, after controlling for confounding factors, 10% of pediatric trauma victims receiving TXA showed a 27% reduction in mortality (Eckert et al., 2014). Nevertheless, its use remains off-label and rare (0.31% in one study; Nishijima et al., 2016).

Tranexamic acid administration has been well documented in nontraumatic pediatric conditions and surgical procedures, cardiac surgery (Grassin-Delyle et al., 2013), scoliosis surgery, and craniosynostosis repairs (Basta, Stricker, & Taylor, 2012). These studies demonstrate comparable benefits with those found in adult patients. There is significant disparity in dosing, indications, and contraindications among pediatric centers. It has also been utilized in menstrual disorders and congenital bleeding disorders (Albiani, Hodge, Pan, Urton, & Clarke, 2008). Although rare, adverse effects have been identified: dizziness, myalgias, seizures, and hypotension with rapid intravenous administration. The theoretical risk of thrombosis has not been identified despite large doses common to pediatric cardiac and spinal surgeries.

Despite increasing evidence supporting mortality benefits in TXA usage in children, there remains a lack of evidence for using a specific dose in the pediatric trauma population. It may not be appropriate to extrapolate results from adults to the pediatric population because children differ from adults in physiology and pharmacokinetics. Moreover, although TXA is frequently used in congenital heart surgeries, its effects in pediatric trauma may be quite different. The purpose of this study was therefore to determine current practices for TXA administration in pediatric trauma patients in the United States to establish appropriate dosage guidelines in pediatric traumatic events.

METHODS

After institutional review board approval, our survey was created and administered via a secure Internet-based survey tool. The validity of the survey tool was verified by nonparticipating practitioners at several regional centers. The survey was sent out via e-mail to the trauma medical directors and trauma program managers at the 363 American College of Surgeons (ACS) Adult and Pediatric Level I and II trauma centers in the United States, as of July 2017 (ACS, 2017). Multiple additional e-mail reminders and follow-up phone calls were conducted before the study was completed in April 2018. All survey participants completed a minimum of five questions; if they identified as not treating pediatric trauma patients, their participation was completed. Facilities identified as treating pediatric trauma patients completed an additional 12 questions (Figure 1). Survey data were tabulated using Excel (Microsoft Corp, Redmond, WA).

RESULTS

Demographics

There were 363 eligible Level I and II facilities, of which 220 responded for a 61% response rate. Of the 99 verified pediatric trauma centers, 80 responded for an 81% response rate. Of the respondents, 97 were adult Level I centers, 79 adult Level II centers, 43 pediatric Level I centers, and 35 pediatric Level II centers. Overall, 148 (67%) reported that they care for pediatric trauma patients. These centers reported caring for an average of 513 pediatric trauma patients annually.

TXA Utilization

Of the centers identified as treating pediatric trauma patients, 52 (35%) report using TXA. An additional 35 centers (25%) reported using TXA only in adult trauma patients. Of note, the pediatric centers' annual trauma volume utilizing TXA was higher, 725 (TXA) versus 437 (non-TXA), suggesting increased patient volume may lead to usage.

The most common initial dosing was 15 mg/kg (68%), interquartile range (IQR) = 5–100 mg/kg. Three programs reported utilizing the standard adult dosing of 1000 mg.

Name of facility:
Annual pediatric trauma volume:
Annual hospital trauma volume:
Using TXA: Yes No
Dosing utilized: _____mg/kg or standard _____mg
Time window for administration: Less than 1 hr Less than 3 hr other_____
Age range: Less than 14 years Less than 18 years Other_____
Follow-up infusion: Yes No
Duration of infusion:_____hr
Dosing of infusion:_____mg
Indications: Compressible hemorrhage Noncompressible hemorrhage Both
Where is TXA given: ED OR ICU
Exclusion criteria utilized: Seizures Color blindness Other

Figure 1. Pediatric TXA survey. ED = emergency department; ICU = intensive care unit; OR = operating room; TXA = tranexamic acid.

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A follow-up infusion was utilized by 45 (87%) of the programs. The most common infusion dosing was 2 mg/kg/hr utilized by 24 centers (54%). There was a disparity among the age declared as pediatric patients by the centers. The survey divided the responses in three categories: age less than 14 years (n = 6; 12%), age less than 15 years (n = 12; 24%), and age less than 18 years (n = 34; 64%). There was also variation in time from injury till administration. The standard recommendation from CRASH-2 (CRASH-2 Collaborators, Shakur et al., 2010) was administration within 3 hr of injury. This was utilized by 40 centers (76%); the remaining 12 utilizing centers' (24%) guidelines recommend administration within 1 hr of injury.

Indication for administration was divided into three categories of hemorrhage with responses: compressible (n = 1; 2%), noncompressible (n = 8; 15%), and both (compressible and noncompressible; n = 43; 83%). Contraindications were divided into three responses: seizures (n = 1; 2%), color blindness (n = 3; 6%), and none (n = 36; 67%). There was also a comment box for additional contraindications, which included pregnancy, traumatic brain injury, known thromboembolic event, and normal thromboelastography (TEG). See Table 1 for existing TXA indications, contraindications, and adverse effects.

TABLE 1 Existing TXA Indications, Contraindications, and Adverse Effects

Indications
Prophylactic/treatment of trauma or surgery with "major" bleeding/hemorrhage expected
Prophylactic/treatment with "mild/moderate" bleeding
Strong desire to avoid transfusion or blood not an option
Preexisting anemia or coagulopathy
Preexisting hypofibrinogenemia
Role for controlling bleeding in patients treated with inhibitors of platelet function and new oral anticoagulants
Difficult to cross-match because of antibodies
Contraindications
Absolute
Hypersensitivity
Active thromboembolic disease
Fibrinolytic conditions with consumption coagulopathy
Relative
The risk–benefit ratio needs to be considered
Renal impairment/dysfunction (dose adjustment required because of the risk of accumulation)
Acquired or inherited disorder of thrombosis
Preexisting coagulopathy or oral anticoagulants
Adverse events
Rare: 1/10,000 to <1/1,000
Allergic skin reactions
Hypotension (with fast intravenous injection)
Digestive effects such as nausea, vomiting, and diarrhea
Color vision disturbances
Very rare: <1/10,000
Thromboembolic events (but is a clot stabilizer, not clot promoter)
Convulsions (with high doses)
Hypersensitivity reactions including anaphylaxis

DISCUSSION

The use of the antifibrinolytic agent TXA in the bleeding trauma patients has expanded significantly since CRASH-2, the randomized placebo-controlled trial that was published in 2010, and the retrospective observational study in the military setting, the 2012 MATTERS study. Because of these promising adult data and their use in nontraumatic bleeding in pediatric surgical patients (with highly variable dosing regimens), TXA has the potential to aid hemostatic resuscitation of the hemorrhaging pediatric trauma patient. Furthermore, the optimal dosing strategy of TXA has not yet been defined.

The best available evidence supporting the use of TXA in pediatric trauma patients is the PED-TRAX study (Eckert et al., 2014). This 2014 observational study included 766 patients younger than 18 years in a combat setting. It revealed that although TXA was used in less than 10% of pediatric trauma victims, primarily in the setting of severe abdominal or extremity trauma, it imparted a decrease in mortality without any complications related to its administration.

The intraoperative use of TXA in the adult patient population is well established. Currently, it has been shown to reduce intraoperative and postoperative blood product transfusions of both packed red blood cells and fresh frozen plasma within 24 hr without an increase in morbidity and thrombotic complications. For example, several meta-analysis studies have demonstrated efficacy to reduce blood loss and risk of transfusion following primary total hip arthroplasty (Fillingham et al., 2018) and reduced blood loss and transfusion on off-pump coronary artery bypass surgery (Dai, Chu, Wang, & Liang, 2018).

In the pediatric population, TXA is routinely used preoperatively and intraoperatively to reduce blood loss during craniosynostosis repair, spine surgeries for scoliosis correction, and congenital heart surgery. Although usage is common, dosing regimens are quite varied. A double-blinded study of craniosynostosis patients utilizing a 50-mg/kg bolus, followed by a 5 mg/kg/hr infusion, found 50% lower blood loss and lower transfusion requirements (Goobie et al., 2011). Tranexamic acid is described as being an effective agent at reducing blood loss and need for transfusion and preventing an increase in D-dimer levels without affecting systemic hemostasis during the treatment of craniosynostosis (Kim et al., 2018). In scoliotic patients, a bolus of 100 mg/kg, followed by an

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infusion of 10 mg/kg/hr, found a 41% reduction in blood loss in patients receiving TXA (Sethna et al., 2005).

Furthermore, the administration of TXA was a multivariate predictor of blood loss, as was the American Society of Anesthesiologists physical status, and preoperative platelet count. A large multicenter consortium review of TXA use found that of 35,478 uses, only 110 were for traumatic events (Nishijima et al., 2016). Its primary use was for cardiac surgery (64%), with a mean estimated dose of was 22.4 mg/kg (IQR = 7.3–84.9 mg/kg). Finally, the most commonly identified dosing 15-mg/kg bolus, followed by 2 mg/kg/hr, is identical to the dosing regimen recommended by the Royal College of Paediatrics and Child Health (2012). See Table 2 for a summary of our survey findings.

Limitations

There were several limitations to our study. Our survey did not examine outcome data for pediatric trauma patients receiving TXA. We were merely examining the incidence and administration practices of centers utilizing the medication. Although our survey was addressed to the trauma program manager or medical director, there was a possibility that another party completed the survey, resulting in inaccurate data. There is significant variability on how a pediatric patient is defined; some centers utilize age, whereas others utilize weight. As a compromise in our recommendations, we utilized a weight of less than 66 kg for pediatric patients. Furthermore, we did not evaluate the barriers preventing centers were from using TXA in pediatric trauma.

Coagulopathy in Pediatric Trauma Patients

Pediatric trauma patients may be more susceptible to hemorrhage when coagulant maturity lags behind its anticoagulant counterpart (Beno et al., 2014). Concerns over hyperfibrinolysis and coagulopathy in children (Whittaker et al., 2013) and adults (Talving et al., 2011) with traumatic brain injuries have been well discussed in previous literature. The incidence has been reported to range from 15% to 87% (Holmes, Goodwin, Land, & Kuppermann, 2001) and is commonly associated with a Glasgow Coma Scale score of 13 or less, low systolic blood pressure, open/multiple fractures, and major tissue defects. In patients requiring transfusion, coagulopathy was present, possibly more common than in adults. The role of hyperfibrinolysis in pediatric trauma patients has not been well established. There are also certainly concerns over fibrinolysis shutdown (Meizoso et al., 2018; Moore et al., 2017), and consideration should be given to selective administration of TXA to patients with hyperfibrinolysis and shutdown. Evaluation of TXA, as part of a balanced resuscitation with readily available blood products, such as those utilized in most centers treating pediatric patients, should also be performed. The early use of TEG should also be considered if possible. Rapid TEG has demonstrated value in assisting with hemostatic resuscitation in pediatric trauma patients (Vogel, Radwan, Cox, & Cotton, 2013).

TABLE 2 Summary of Survey Findings

Indications for Administration	
Compressible and noncompressible hemorrhage	
Age <18 years	
Within 3 hr of injury	
Dosing	
Loading Dose	**Follow-Up Infusion**
Weight >66 kg: 1 g intravenously over 10 min	1 g intravenous infusion over 8 hr
Weight <66 kg: 15 mg/kg intravenously over 10 min	2 mg/kg/hr intravenous infusion over 8 hr

KEY POINTS

- While the clinical evidence for TXA use in pediatric trauma patients is limited, consideration should be given for its use in major trauma with hemodynamic instability or significant risk for ongoing hemorrhage.
- If available, resuscitation should be guided by TEG to identify candidates with thrombolysis (elevated LY30) that would most benefit from administration. This represents a low-cost, low-risk, and high-yield therapy for pediatric trauma patients.
- Summary of Recommendations: Bolus 15 mg/kg, infusion 2 mg/kg/hr over 8 hr, age less than 18 years, administered in less than 3 hr, indicated for compressible (able to be occluded with manual pressure or device) and noncompressible hemorrhage.

CONCLUSION

There is consistent coagulation system response to tissue injury across the age continuum. We believe that there is sufficient evidence to utilize TXA in pediatric trauma patients, particularly those with persistent hemorrhage and hemodynamic instability. The consideration and utilization of this relatively cost-effective therapy may prove beneficial for pediatric trauma patients as it has been in pediatric nontrauma patients. Our research indicates that a standardized protocol for TXA use in pediatric trauma patients is necessary. The first step is the need to define a pediatric patient because research has shown the cutoff age to vary. There is also a need for a specific dosage and administration regimen and specific inclusion and exclusion criteria. Although approximately 68% of hospitals are using the same initial dose, only 54% use the same infusion dose, which could create a large variation in this drug's results. Contraindications or precautions to the drug are also not being considered as exclusion criteria in most cases.

Standardization and research are needed to utilize this medication to its best potential. The TIC-TOC trial is currently

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enrolling participants in its pilot pediatric TXA study and will evaluate the viability of a large-scale trial (Nishijima et al., 2018). Although our study did not evaluate why many hospitals are not using TXA, having a set protocol may increase the usage of this potentially lifesaving drug in pediatric trauma patients. Multiple questions remain regarding the use of antifibrinolytics in critically bleeding trauma patients, both adult and pediatric. Further investigations regarding indications, dosing, and contraindications remain to be seen and will be of great interest to the trauma community.

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