VOLUME - 14, ISSUE - 01, JANUARY - 2025 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

General Surgery

PROSPECTIVE COMPARATIVE STUDY OF ONLY BLOOD TRANSFUSION VS TRANEXAMIC ACID WITH BLOOD TRANSFUSION IN TRAUMA PATIENTS WITH SHOCK

Prof. Dr. B. Santhi Director, Institute Of General Surgery, Madras Medical College, Chennai, Tamilnadu, India 600003

Dr. Karthikeyan. S Postgraduate, Institute of General Surgery, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai

ABSTRACT Trauma-induced hemorrhage is a leading cause of preventable death worldwide, with hemorrhagic shock being particularly fatal without timely intervention. This study aims to compare outcomes in trauma patients treated with only blood transfusion versus those treated with a combination of tranexamic acid (TXA) and blood transfusion at Rajiv Gandhi Government General Hospital, Chennai. Hemodynamic stability markers such as blood pressure, pulse rate, and the Modified Shock Index (MSI) are evaluated alongside blood transfusion needs, ICU admissions, and mortality rates. Current global trauma care protocols highlight the integration of TXA for its antifibrinolytic benefits, particularly in stabilizing fibrin clots and reducing mortality from bleeding when administered within three hours post-injury. The CRASH-2 and MATTERs trials have established TXA's efficacy in both civilian and military settings, supporting its inclusion in massive transfusion protocols (MTP) for trauma patients with hemorrhagic shock. This prospective study will help inform trauma care guidelines, especially in resource-limited settings, by assessing whether combined TXA and transfusion therapy can improve patient outcomes, reduce ICU stays, and minimize the need for additional transfusion.

KEYWORDS : Massive Transfusion Protocol, Thromboelastography, Multiple Organ Dysfunction Syndrome, Transfusion-Related Acute Lung Injury, Tranexamic Acid, Modified Shock Index

INTRODUCTION

Trauma is a leading cause of death worldwide, particularly among younger populations. According to the World Health Organization (WHO), over 5 million people die annually due to traumatic injuries, accounting for nearly 9% of global mortality. Road traffic accidents, falls, and violent injuries are among the most common causes of trauma.

Hemorrhage, or excessive bleeding, is the primary cause of preventable death in trauma patients. Uncontrolled bleeding leads to hemorrhagic shock, which results in inadequate tissue perfusion and can progress to organ failure and death if not treated promptly.In trauma care, controlling bleeding is the first priority to prevent rapid deterioration. The body's natural response to trauma-induced bleeding involves the coagulation system, which works to form clots and stop the bleeding. However, in cases of severe trauma, this system may become overwhelmed, leading to a phenomenon known as trauma-induced coagulopathy (TIC). TIC involves excessive clot breakdown (hyperfibrinolysis), resulting in the inability to form stable blood clots, which exacerbates blood loss. Hemorrhagic shock, coupled with TIC, requires rapid intervention, including blood transfusion, resuscitative measures, and hemostatic agents to improve patient outcomes.

While blood transfusions are lifesaving, they are not without risks. Complications such as transfusion-related acute lung injury (TRALI), infections, and electrolyte imbalances can arise from the administration of blood products. Furthermore, transfusions alone may not adequately address the underlying hyperfibrinolytic state seen in many trauma patients. Use of tranexamic acid (TXA), an antifibrinolytic agent that helps to reduce bleeding by preventing the breakdown of fibrin clots. TXA works by inhibiting plasminogen activation, which is responsible for breaking down fibrin, the main protein that stabilizes blood clots. By preventing clot degradation, TXA can promote hemostasis in trauma patients experiencing hyperfibrinolysis.

Despite the growing evidence supporting the use of TXA, there remains a need to investigate how TXA works in conjunction with standard blood transfusions in civilian trauma settings. Most studies have focused on the administration of TXA alone, with little attention given to its role as part of a combined therapeutic approach. Understanding whether the addition of TXA to blood transfusion protocols can lead to better outcomes, such as reducing the number of blood units needed, lowering ICU admissions, or improving survival, is critical to refining trauma care.

India, like many other low- and middle-income countries, faces a significant burden of trauma, particularly from road traffic accidents. The National Crime Records Bureau (NCRB) of India reports that road traffic accidents account for more than 150,000 deaths annually, with a large proportion of these deaths resulting from hemorrhage. Despite the widespread use of blood transfusions in trauma care across India, the integration of TXA into these protocols has not been universally adopted. Many trauma centers still rely heavily on transfusions alone, without incorporating antifibrinolytic agents as part of their treatment strategy.

Aims and Objectives

1. To study and compare the outcomes of only blood transfusion vs. tranexamic acid with blood transfusion in trauma patients with shock.
2. Measure blood pressure, pulse rate, modified shock index, and urine output.
3. Determine further need for blood transfusion and ICU admission.

MATERIAL AND METHODS

Study Design

This study is a prospective, comparative observational study designed to evaluate the outcomes of trauma patients in shock receiving only blood transfusion compared to those receiving both blood transfusion and tranexamic acid (TXA). The study aims to determine the effectiveness of TXA in conjunction with blood transfusion in reducing the need for further transfusions, ICU admissions, and overall improvement in patient stability.

Study Population

The study will include 120 trauma patients who present with shock and meet the following inclusion and exclusion criteria. Patients will be divided into two groups:
Group A: Patients receiving only blood transfusion.
Group B: Patients receiving both blood transfusion and tranexamic acid (TXA).

Inclusion Criteria

Trauma patients with stable airway and breathing conditions, Both male and female patients aged 12 years and above, Patients received within 3 hours of the trauma event.

Exclusion Criteria

Severe kidney dysfunction, Thromboembolic events, Patients received after 3 hours of trauma, Epilepsy, Patients with pelvic bone fractures or significant injuries to the pelvis.

Study Intervention

Group A (Only Blood Transfusion): Patients in this group will receive the standard trauma protocol, which includes blood transfusions as required for resuscitation and stabilization.

Group B (Blood Transfusion with Tranexamic Acid): In addition to receiving blood transfusions, patients in this group will receive tranexamic acid (TXA)intravenously at a dose of 1 gram administered over 10 minutes, followed by an additional 1 gram over 8 hours if required, as per hospital protocols for trauma patients with significant hemorrhage.

Primary Outcomes:

Blood Pressure Stabilization: Monitoring for sustained improvement in blood pressure.

Pulse Rate: Reduction in pulse rate indicating cardiovascular stabilization.

Modified Shock Index (MSI): A measure of hemodynamic status to assess recovery from shock.

Urine Output: Improvement in urine output as an indicator of renal perfusion and overall fluid status.

Secondary Outcomes:

Need For Additional Blood Transfusions: The number of transfusions required post-intervention.

Icu Admissions: The number of patients requiring admission to the ICU post-intervention.

Mortality Rates: Comparison of mortality rates between the two groups at 6, 12, and 24 hours post-intervention.

Statistical Analysis

Mean Time to Death: This will be calculated for patients who do not survive the intervention, using Kaplan-Meier survival curves.

Comparative Analysis: Student's t-test and chi-square test will be used to compare continuous and categorical variables, respectively, between the two groups.

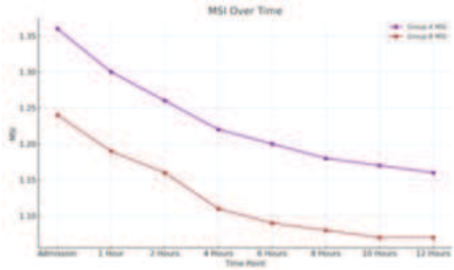
Logistic Regression: To determine the factors influencing ICU admission and mortality, logistic regression will be applied.

Sensitivity Analysis: A sensitivity analysis will be performed to ensure robustness of results, adjusting for confounders such as age, sex, injury type, and injury severity.

The study conducted at the Rajiv Gandhi Government General Hospital (RGGGH), Chennai, a tertiary care hospital with a well-established trauma care unit. The hospital caters to a high volume of trauma patients, providing a conducive environment for evaluating the outcomes of the interventions.

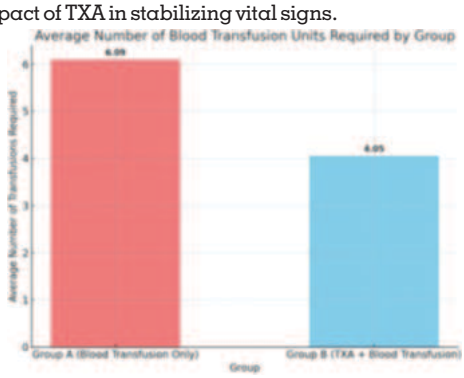
Patients will be followed up for a total of 12 hours post-intervention. Continuous monitoring of vital signs and clinical parameters will be conducted as described. In cases of clinical deterioration, patients will be shifted to the ICU, and outcomes will be recorded.

OBSERVATION & RESULTS



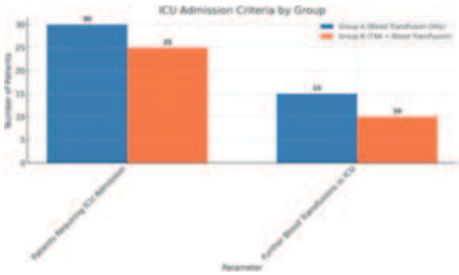
Interpretation:

Group B consistently maintains higher blood pressure and lower pulse rates, demonstrating superior hemodynamic stability. The Modified Shock Index (MSI) is significantly better in Group B across the 12-hour period, with the most notable difference at 12 hours (p-value = 0.005), emphasizing the impact of TXA in stabilizing vital signs.



Interpretation:

Group B (TXA + Blood Transfusion) required significantly fewer blood transfusions than Group A, with an average of 4.05 units compared to 6.09 units in Group A (p-value = 0.02). This reduction highlights the effectiveness of TXA in minimizing blood loss.



Interpretation:

Fewer patients in Group B required ICU admission compared to Group A. Additionally, there was a reduction in the need for additional blood transfusions during the ICU stay in Group B, further supporting the beneficial effects of TXA.

SUMMARY

Interpretation:

The summary of statistical significance shows that there are meaningful differences between the two groups in terms of hemodynamic stability, transfusion needs, ICU admission rates, and 24-hour mortality, all favoring the TXA group

DISCUSSION

In this study, Group B patients (TXA + Blood Transfusion) demonstrated a shorter time to hospital admission, which is critical in improving trauma outcomes, as rapid intervention is often associated with better prognoses. Gruen et al. (2006) identified that delays in trauma intervention significantly contribute to mortality, with their analysis of 2,594 trauma deaths revealing that many could have been prevented with more timely care. Similarly, Evans et al. (2010) emphasized that rapid hospital admission and early intervention are crucial in reducing trauma-related deaths, reinforcing the

importance of timely access to care. This study's findings align with Spahn et al. (2019), who noted that the European guidelines for managing major bleeding in trauma stress the importance of minimizing prehospital time to enhance survival outcomes.

In terms of blood transfusion requirements, Group B required significantly fewer blood transfusions than Group A. The findings are consistent with those of the CRASH-2 trial (Shakur et al., 2010), where TXA use was associated with a reduction in the need for transfusions in patients with severe hemorrhage. Richards et al. (2021) similarly observed that TXA use reduced the number of transfusions required, though they raised concerns about potential complications with higher doses. By minimizing blood transfusions, TXA not only improves resource utilization but also mitigates transfusion-related risks such as Transfusion-Related Acute Lung Injury (TRALI) and Transfusion-Associated Circulatory Overload (TACO) (Valle et al., 2014).

Clinical outcomes in this study showed a significant reduction in 24-hour mortality for Group B, reflecting the established benefits of TXA in trauma patients. The CRASH-2 trial (Shakur et al.,2010) demonstrated a similar reduction in mortality when TXA was administered within three hours of injury. However, Rivas et al. (2021) highlighted concerns about potential thromboembolic events associated with TXA. Although this study did not find significant differences in thromboembolic events between the two groups, Myers et al. (2019) and Moore et al. (2017) noted that TXA could increase the risk of venous thromboembolism (VTE) in certain populations. This underscores the need for careful monitoring for thromboembolic complications in trauma care.

Overall, this study's findings align with previous research showing that TXA improves outcomes in trauma patients by reducing mortality and stabilizing vital parameters.However, as Moore et al. (2017)and Myers et al. (2019)cautioned, the potential for thromboembolic complications must be closely monitored, particularly in patients with preexisting risk factors for thrombosis. Future research should focus on identifying which subgroups of trauma patients are most at risk for adverse events and refining TXA administration protocols to minimize these risks.

CONCLUSION

This study demonstrates the efficacy of tranexamic acid (TXA) combined with blood transfusion in improving outcomes for trauma patients with hemorrhagic shock. When compared to the group receiving only blood transfusions, the TXA group (Group B) showed superior results in terms of hemodynamic stability, reduced need for blood transfusions, better renal perfusion, and, most importantly, lower mortality rates. These findings align with previous research, such as the CRASH-2 trial and other studies that have validated the benefits of early TXA administration in trauma care.

A key finding in this study was the significantly shorter time to hospital admission in the TXA group, which may have contributed to the improved outcomes. Early hospital admission is a critical factor in trauma management, as it allows for rapid intervention, stabilization, and the timely administration of therapies like TXA. This reduction in prehospital time likely enhanced the effectiveness of TXA, as its benefits are maximized when administered within the first three hours after injury, as demonstrated in the CRASH-2 trial.

The TXA group also exhibited greater hemodynamic stability, evidenced by consistently higher blood pressure and lower pulse rates. This suggests that TXA not only helps control bleeding but also stabilizes vital signs, which is crucial in reducing the risk of shock- related complications. The Modified Shock Index (MSI) in the TXA group was significantly improved, further supporting the role of TXA in maintaining hemodynamic balance during trauma resuscitation.

Perhaps the most important outcome of this study is the significantly lower 24-hour mortality rate in the TXA group. This reduction in early mortality reflects TXA's life- saving potential when used as part of a comprehensive trauma resuscitation strategy. Although there are concerns about potential thromboembolic risks with TXA, this study did not observe significant differences in thromboembolic events between the groups.

In conclusion, this study confirms the effectiveness of TXA in improving outcomes for trauma patients with hemorrhagic shock. By stabilizing hemodynamic parameters, reducing transfusion needs, and lowering mortality, TXA has proven to be a valuable addition to trauma protocols. Further research should continue to refine its use, particularly in identifying patient subgroups at risk for thromboembolic events. However, based on the evidence, TXA should be considered a key component of trauma care, particularly in patients with severe hemorrhage.

REFERENCES

1. Richards JE, Fedeles BT, Chow JH, et al. Is Tranexamic acid associated with mortality or multiple organ failure following severe injury?. Shock. 2021;55(1):55–60.
2. CRASH-2 Trial Collaborators, Shakur H, Roberts I, Bautista R, et al. Effects of tranexamic acid on death, vascular occlusive events, and blood transfusion in trauma patients with significant haemorrhage (CRASH-2): a randomised, placebo- controlled trial. Lancet. 2010;376(9734):23–32.
3. Zallen G, Offner PJ, Moore EE, et al. Age of transfused blood is an independent risk factor for postinjury multiple organ failure. Am J Surg. 1999;178(6):570–2.
4. Looney MR, Gropper MA, Matthay MA. Transfusion-related acute lung injury: a review. Chest. 2004;126(1):249–58.
5. World Health Organization. Injuries. Health topics. WISQARS: Leading causes of death reports, national and regional, 1999–2014. 2015.
6. Kauvar DS, Wade CE. Impact of hemorrhage on trauma outcome: an overview of epidemiology, clinical presentations, and therapeutic considerations. J Trauma. 2006;60(6 Suppl)–11.
7. Sauaia A, Moore FA, Moore EE, et al. Epidemiology of trauma deaths: a reassessment. J Trauma. 1995;38(2):185–93.
8. Paudyal P, Smith J, Robinson M, et al. Tranexamic acid in major trauma: implementation and evaluation across South West England. Eur J Emerg Med. 2017.
9. Moore EE. Orr Memorial Lecture. Staged laparotomy for the hypothermia, acidosis, and coagulopathy syndrome. Am J Surg. 1996;172(5):405–10.
10. Bolliger D, Seeberger MD, Tanaka KA. Principles and practice of thromboelastography in clinical coagulation management and transfusion practice. Transfus Med Rev. 2012;26(1):1–13.
11. Rahe-Meyer N, Pichlmaier U, Haverich A, et al. Thromboelastometry-guided administration of fibrinogen concentrate for the treatment of excessive intraoperative bleeding in thoracoabdominal aortic aneurysm surgery. J Thorac Cardiovasc Surg. 2009;138(3):694–702.
12. Inaba K, Branco BC, Rhee P, et al. Impact of plasma transfusion in trauma patients who do not require massive transfusion. J Am Coll Surg. 2010;210(6):957–65.
13. Allain JP, Stramer SL, Carneiro-Proietti AB, et al. Transfusion-transmitted infectious diseases. Biologicals. 2009;37(2):71–7.
14. Alter HJ, Klein HG. The hazards of blood transfusion in historical perspective. Blood. 2008;112(7):2617–26.
15. Silliman CC, Ambruso DR, Boshkov LK. Transfusion-related acute lung injury. Blood. 2005;105(6):2266–73.