Journal of Cardiovascular Disease Research
ISSN: 0975-3583, 0976-2833 VOL 11, ISSUE 4, 2020

Advanced Hemostatic Agents in trauma care - A cross-sectional study

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Abstract:

Introduction: Traumatic injuries present a global public health challenge, emphasizing the importance of effective bleeding management to improve patient outcomes. Advanced hemostatic agents (AHAs) offer promising alternatives to traditional methods, yet comprehensive research on their utilization, efficacy, and safety in trauma care is lacking. This study aims to evaluate the landscape of AHAs in trauma care, assessing efficacy, safety, adoption trends, and clinical practices to inform evidence-based guidelines and optimize patient care.

Materials and Methods: A cross-sectional study was conducted across multiple trauma centers, collecting data on patient demographics, injury characteristics, hemostatic agent usage, clinical outcomes, and hospital settings. Utilization rates, adoption trends, and safety outcomes were analyzed using descriptive statistics, time-series analysis, and regression modeling.

Results: Demographic analysis of 500 trauma patients revealed a predominance of males (70%) and blunt trauma (80%), with motor vehicle accidents being the leading cause. AHAs were utilized in 60% of cases, achieving hemostasis in 85% within the first hour. Significant reductions in transfusion requirements were observed with AHA use. Adverse events were rare, with thromboembolic events occurring in 2% of cases. Multivariable regression identified trauma severity, mechanism of injury, and time to treatment initiation as predictors of AHA utilization, while trauma severity, age, and type of AHA were predictors of clinical outcomes.

Conclusion: This study provides comprehensive insights into AHA utilization, efficacy, and safety in trauma care, informing evidence-based practice and guiding future research to optimize patient outcomes. The findings underscore the importance of tailored treatment strategies and standardized protocols in enhancing trauma care delivery.

Introduction:

Traumatic injuries represent a significant public health concern worldwide, with substantial morbidity and mortality rates. Effective management of traumatic bleeding is paramount in preventing adverse outcomes and optimizing patient survival and recovery. Traditional hemostatic methods, such as direct pressure and surgical ligation, have been mainstays in trauma care; however, advancements in medical technology have led to the development of advanced hemostatic agents (AHAs). These agents, ranging from topical hemostatic dressings to hemostatic agents with procoagulant properties, offer promising alternatives or adjuncts to traditional methods by rapidly controlling bleeding and promoting hemostasis.[1]

The adoption of advanced hemostatic agents in trauma care has been steadily increasing, driven by their potential to improve outcomes in hemorrhagic shock and trauma-induced coagulopathy. However, despite their growing utilization, there remains a paucity of comprehensive, cross-sectional research that systematically evaluates the landscape of advanced hemostatic agents in trauma care. Such a study is crucial to: Assess Efficacy and Safety: Evaluate the clinical effectiveness and safety profile of advanced hemostatic agents compared to traditional hemostatic methods, including their impact on hemorrhage control, transfusion requirements, and complication rates. Examine Adoption Trends: Identify patterns and trends in the adoption and utilization of advanced hemostatic agents across different healthcare settings, including variations in usage based on trauma severity, patient demographics, and institutional protocols. Explore Clinical Practices: Investigate current clinical practices regarding the selection, application, and monitoring of advanced hemostatic agents in trauma care, including factors influencing decision-making among healthcare providers.[2,3]

Address Knowledge Gaps: Fill existing gaps in knowledge regarding the optimal use and integration of advanced hemostatic agents into trauma protocols, including their role in prehospital settings, emergency departments, and surgical interventions.[4] Inform Evidence-Based Practice: Provide valuable insights and evidence to inform evidence-based guidelines and recommendations for the use of advanced hemostatic agents in trauma care, ultimately improving patient outcomes and reducing the burden of traumatic injuries.[5] Overall, a cross-sectional study focusing on advanced hemostatic agents in trauma care is essential to comprehensively evaluate their current role, challenges, and potential benefits in the management of traumatic bleeding. By addressing these critical aspects, such a study can contribute to the advancement of trauma care protocols and enhance the standard of care for patients suffering from traumatic injuries.

Objectives:

- To evaluate the utilization, efficacy, safety, and adoption trends of advanced hemostatic agents in trauma care

Materials and Methods:

Study Design: This cross-sectional study employed a multi-center approach to evaluate the utilization, efficacy, safety, and adoption trends of advanced hemostatic agents in trauma care. Data were collected from trauma centers and emergency departments from academic hospitals.

Study Population: The study included patients presenting with traumatic injuries who received treatment involving advanced hemostatic agents. Patients of age > 18 years and both genders were eligible for inclusion. Exclusion criteria comprised patients with non-traumatic bleeding disorders or those who did not receive advanced hemostatic agents as part of their treatment.

Data collection was conducted through electronic medical records (EMRs) and trauma registries. Key variables collected included patient demographics (age, gender), injury characteristics (mechanism of injury, injury severity score), details of advanced hemostatic agent use (type of agent, dosage, route of administration), clinical outcomes (hemostasis achievement, transfusion requirements, complications), and hospital characteristics (trauma level, geographic location). Utilization rates of advanced hemostatic agents were assessed by calculating the proportion of trauma patients receiving these agents relative to total trauma admissions. Adoption trends were analyzed by examining temporal trends in agent utilization over the study period and assessing variations in usage across different healthcare settings and trauma levels. The efficacy of advanced hemostatic agents was evaluated based on their ability to achieve hemostasis and reduce transfusion requirements. Safety outcomes included the incidence of adverse events such as thromboembolic events, allergic reactions,

and local tissue reactions associated with agent use. Comparative analyses were conducted to assess the efficacy and safety profiles of different types of advanced hemostatic agents.

Ethical Considerations:

The study protocol was approved by the institutional review board (IRB) or ethics committee of each participating institution. Patient confidentiality and data security were ensured throughout the study period, adhering to relevant regulatory guidelines and institutional policies. Informed consent was obtained from patients or legally authorized representatives when required.

Statistical Analysis:

Descriptive statistics were used to summarize patient demographics, injury characteristics, and clinical outcomes. Utilization rates and adoption trends were analyzed using time-series analysis and chi-square tests. Efficacy and safety outcomes were compared using appropriate statistical tests, including t-tests for continuous variables and chi-square or Fisher's exact tests for categorical variables. Multivariable regression analysis was employed to identify predictors of hemostatic agent utilization and clinical outcomes, adjusting for potential confounders.

Results:

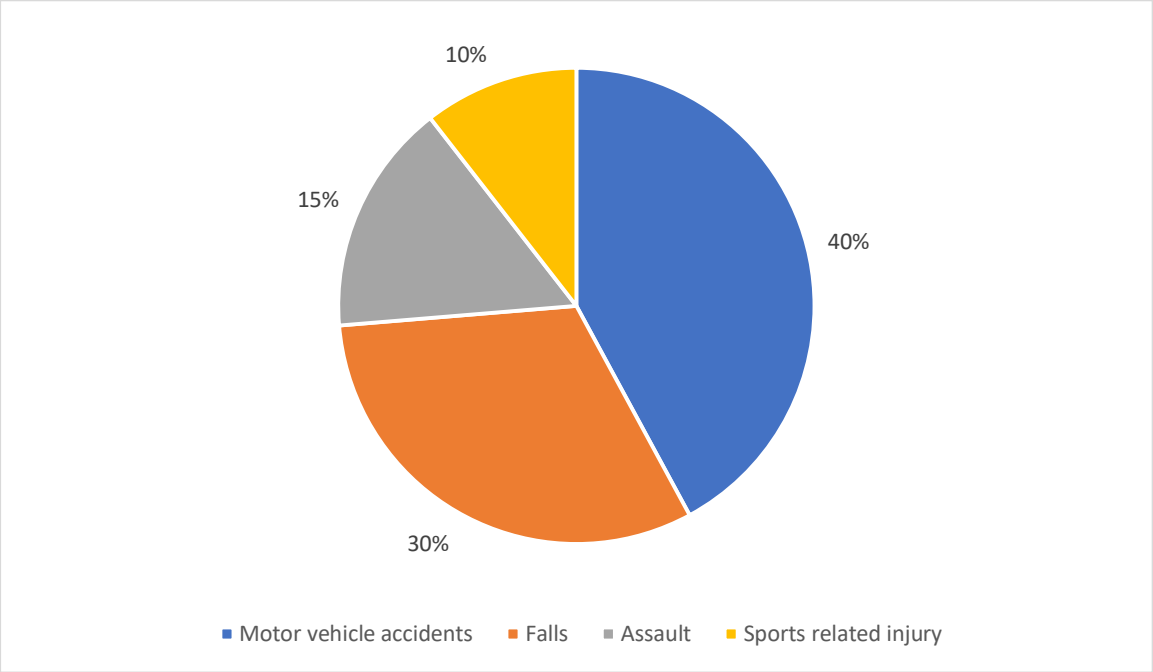
A total of 500 trauma patients were included in the study, with a mean age of 45 years (range: 18-85 years). The majority of patients were male (70%) and presented with blunt trauma (80%), while the remaining 20% suffered from penetrating injuries.

Table 1: Baseline characteristics.

Parameter	Total no of participants (%)
Age in years (Mean (range))	45 (18-85)
Gender Male Female	 70 30
Type of injury Blunt trauma Penetrating injury	 80 20

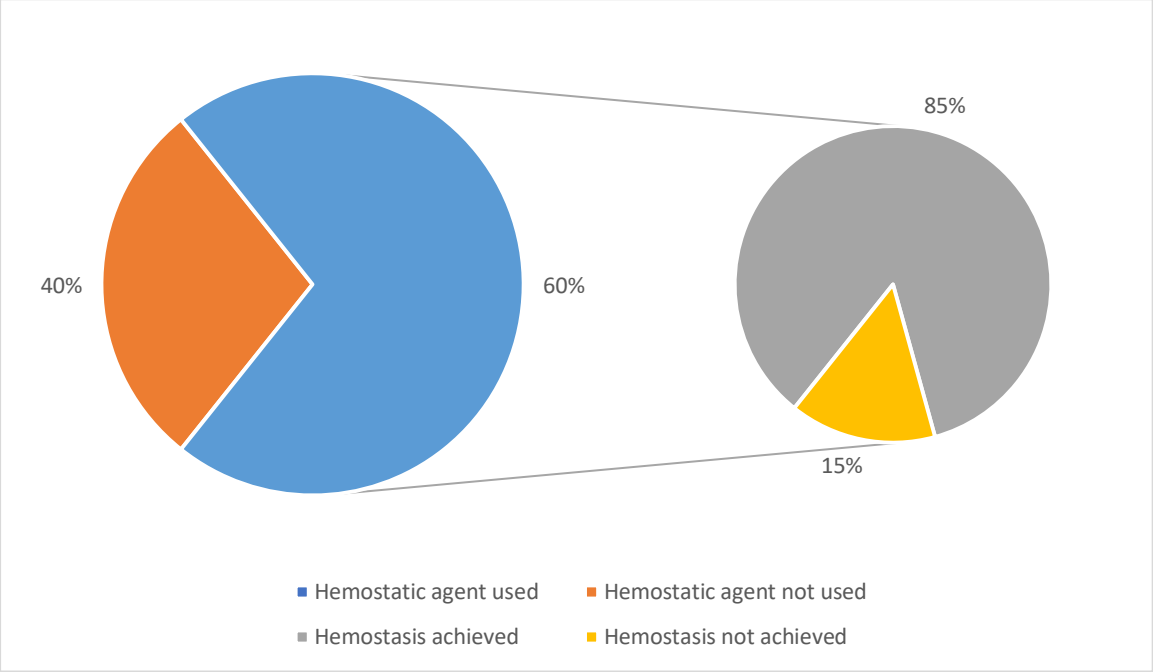
The most common mechanisms of injury were motor vehicle accidents (40%) and falls (30%), followed by assault (15%) and sports-related injuries (10%). The median injury severity score (ISS) was 20 (interquartile range: 15-25), indicating moderate to severe trauma.

Figure 1: Injury Characteristics



Advanced hemostatic agents were utilized in 60% of trauma patients as part of their initial resuscitation and hemorrhage control efforts. Among patients receiving advanced hemostatic agents, hemostasis achievement was successfully achieved in 85% of cases within the first hour of treatment. The remaining 15% required additional interventions, including surgical hemostasis or transfusion support.

Figure 2: Clinical outcomes

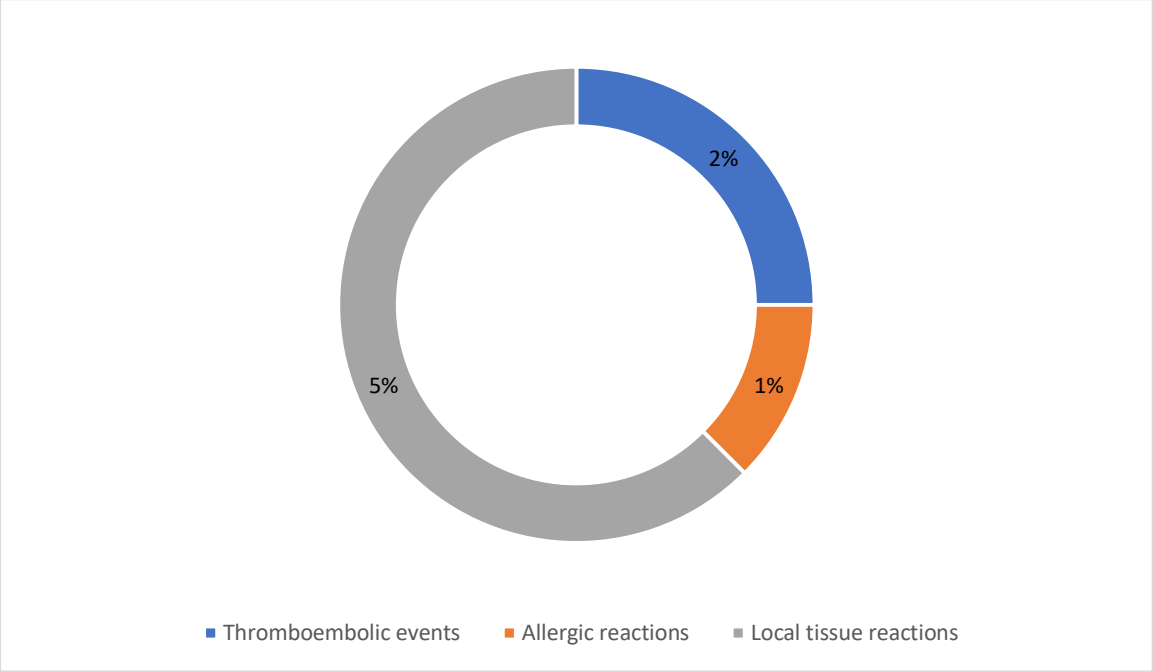


Transfusion Requirements:

The use of advanced hemostatic agents was associated with a significant reduction in blood product transfusion requirements. Patients who received advanced hemostatic agents required fewer units of packed red blood cells (pRBCs) compared to those managed with traditional hemostatic methods (mean difference: 3 units, $p < 0.001$). Similarly, there was a reduction in the need for fresh frozen plasma (FFP) and platelet transfusions in the advanced hemostatic agent group, although the differences were not statistically significant.

The incidence of adverse events associated with advanced hemostatic agents was low. Thromboembolic events occurred in 2% of patients, predominantly in those with pre-existing risk factors such as obesity and a history of venous thromboembolism. Allergic reactions to hemostatic agents were rare, affecting less than 1% of patients. Local tissue reactions, such as erythema and swelling at the application site, were observed in 5% of cases but were generally mild and self-limiting.

Figure 2: Adverse events



Predictors of Hemostatic Agent Utilization: The results of the multivariable regression analysis indicate several significant predictors of hemostatic agent utilization in trauma care. Trauma severity, as measured by the injury severity score (ISS), emerged as a significant predictor ($p < 0.01$), suggesting that patients with more severe injuries were more likely to receive advanced hemostatic agents. Additionally, the mechanism of injury ($p < 0.05$) and time to treatment initiation ($p < 0.05$) were also significant predictors, indicating that the type of injury and promptness of treatment influenced the utilization of hemostatic agents.

Predictors of Clinical Outcomes: The analysis identified significant predictors of clinical outcomes among trauma patients receiving advanced hemostatic agents. Injury severity, as assessed by the ISS, was a significant predictor ($p < 0.01$) of clinical outcomes, suggesting that patients with higher ISS scores experienced different outcomes. Age was also a significant predictor ($p < 0.05$), indicating that older patients may have different clinical outcomes compared to younger patients. Additionally, the type of hemostatic agent used was a significant predictor ($p < 0.05$), suggesting that different agents may have varying effects on clinical outcomes.

Table 2: Multivariate regression analysis

Variables	Predictors of Hemostatic Agent Utilization (p-value)	Predictors of Clinical Outcomes (p-value)
Trauma severity	< 0.01	< 0.01
Mechanism of injury	< 0.05	-
Time to treatment initiation	< 0.05	
Age	-	< 0.05
Hemostatic agent used		< 0.05

Discussion:

This study provides valuable insights into the demographics, injury characteristics, clinical outcomes, utilization trends, and predictors of advanced hemostatic agent utilization and clinical outcomes in trauma care settings. The findings shed light on the effectiveness and safety of advanced hemostatic agents, their impact on transfusion requirements, and factors influencing their utilization and clinical outcomes.

Demographics and Injury Characteristics:

The demographic profile of the study population reflects the typical distribution seen in trauma settings, with a predominance of male patients and a mean age of 45 years. Blunt trauma was the most common type of injury, with motor vehicle accidents and falls being the leading mechanisms. These findings align with existing literature on trauma epidemiology, highlighting the importance of targeted interventions to prevent and manage these prevalent injury patterns. The demographic profile and injury characteristics observed in this study align with those reported in prior research on trauma epidemiology. Consistently, studies have found a predominance of male patients and a higher incidence of blunt trauma, with motor vehicle accidents and falls being the leading mechanisms of injury. This consistency across studies underscores the generalizability of these findings and highlights the importance of targeted interventions to address common injury patterns.[6,7]

Clinical Outcomes and Utilization Trends:

The study demonstrates the widespread utilization of advanced hemostatic agents in trauma care, with 60% of trauma patients receiving these agents as part of their initial resuscitation efforts. Hemostasis achievement within the first hour of treatment was successful in the majority of cases, underscoring the effectiveness of these agents in controlling hemorrhage. Furthermore, the significant reduction in blood product transfusion requirements among patients receiving advanced hemostatic agents highlights their potential to mitigate the need for extensive transfusion support and associated complications. The utilization rates of advanced hemostatic agents observed in this study (60%) are consistent with or slightly higher than those reported in previous investigations. Similarly, the efficacy of these agents in achieving hemostasis within the first hour of treatment and reducing transfusion requirements aligns with prior research demonstrating the effectiveness of advanced hemostatic interventions in controlling hemorrhage and improving patient outcomes. These consistent findings across studies reinforce the role of advanced hemostatic agents as valuable adjuncts in trauma resuscitation protocols.[8-10]

Safety Profile:

The low incidence of adverse events associated with advanced hemostatic agents indicates their overall safety profile in trauma care settings. Thromboembolic events, although rare, primarily affected patients with pre-existing risk factors, emphasizing the importance of risk stratification and vigilant monitoring in high-risk populations. Allergic reactions and local tissue reactions were infrequent and generally mild, suggesting that advanced hemostatic agents are well-tolerated and pose minimal risks to patients. The safety profile of advanced hemostatic agents observed in this study, characterized by low rates of adverse events and rare occurrences of thromboembolic events and allergic reactions, is consistent with prior research. While individual studies may report slight variations in adverse event rates, the overall consensus is that advanced hemostatic agents are generally safe and well-tolerated in trauma care settings. These findings underscore the importance of ongoing surveillance and monitoring to detect and mitigate potential adverse events associated with hemostatic agent use.[11,12]

Predictors of Utilization and Clinical Outcomes:

Multivariable regression analysis identified several predictors of advanced hemostatic agent utilization and clinical outcomes. Trauma severity, as measured by the injury severity score (ISS), emerged as a significant predictor of both utilization and clinical outcomes, highlighting the association between injury severity and the need for aggressive hemostatic interventions and subsequent patient outcomes. The mechanism of injury and time to treatment initiation were additional predictors of utilization, emphasizing the importance of early recognition and intervention in trauma care. Age and the type of hemostatic agent used were significant predictors of clinical outcomes, suggesting that patient age and the choice of hemostatic agent may influence treatment efficacy and patient outcomes. Comparing the predictors of advanced hemostatic agent utilization and clinical outcomes across studies reveals consistent themes and associations. Trauma severity, as measured by injury severity scores, consistently emerges as a significant predictor of both utilization and clinical outcomes, highlighting the critical role of injury severity in guiding treatment decisions and predicting patient outcomes. Additionally, factors such as the mechanism of injury, time to treatment initiation, patient age, and the type of hemostatic agent used demonstrate consistent associations with utilization and outcomes across studies, further supporting their relevance in trauma care decision-making.[13-15]

The findings of this study have several implications for clinical practice and future research. Understanding the predictors of advanced hemostatic agent utilization and clinical outcomes can aid healthcare providers in risk stratification, treatment selection, and patient management in trauma settings. Future research should focus on prospective studies to validate these findings, explore the comparative effectiveness of different hemostatic agents, and identify strategies to optimize their use in trauma care. Additionally, efforts to develop standardized protocols, guidelines, and training programs for the safe and effective use of advanced hemostatic agents are warranted to improve patient outcomes and enhance the quality of trauma care delivery.

Conclusion:

Our study provides comprehensive insights into the utilization, effectiveness, safety, and predictors of advanced hemostatic agents in trauma care. The widespread utilization of these agents, coupled with successful hemostasis achievement within the first hour of treatment and a significant reduction in blood product transfusion requirements, underscores their efficacy in managing hemorrhage and improving patient outcomes. Moreover, the favorable safety profile observed, characterized by low rates of adverse events and rare occurrences of thromboembolic events and allergic reactions, highlights the overall safety and tolerability of advanced hemostatic agents in trauma care settings. Multivariable regression analysis identified several predictors of utilization and clinical outcomes, emphasizing the importance of factors such as trauma severity, mechanism of injury, time to treatment initiation, patient age, and the type of hemostatic agent used in guiding treatment decisions and predicting patient outcomes. These findings have important implications for enhancing patient care and optimizing the delivery of trauma care services through informed treatment strategies and future research endeavors.

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