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A High FFP:PRBC Transfusion Ratio Decreases Mortality in All Massively Transfused Trauma Patients Regardless of Admission INR

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Abstract

Background—Coagulopathy is present in 25-38% of trauma patients upon arrival to the hospital and these patients are four times more likely to die than trauma patients without coagulopathy. Recently, a high ratio of fresh frozen plasma (FFP) to packed red blood cells (PRBCs) has been shown to decrease mortality in massively transfused trauma patients. Therefore, we hypothesized that patients with elevated INR on arrival to the hospital may benefit more from transfusion with a high ratio of FFP:PRBC than those with a lower INR.

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Methods—Retrospective multicenter cohort study of 437 massively transfused trauma patients. To determine if the effect of the ratio of FFP:PRBC on death at 24 hours is modified by a patient's admission INR on arrival to the hospital we used contingency tables and logistic regression.

Results—Trauma patients who arrived to the hospital with an elevated INR had a greater risk of death than those with a lower INR. However, as the ratio of FFP:PRBC transfused increased, mortality decreased similarly between the INR quartiles.

Conclusions—The mortality benefit from a high FFP:PRBC ratio is similar for all massively transfused trauma patients. This is contrary to the current belief that only coagulopathic trauma patients benefit from a high FFP:PRBC ratio. Furthermore, it is unnecessary to determine whether INR is elevated before transfusing a high FFP:PRBC ratio. Future studies are needed to determine the mechanism by which a high FFP:PRBC ratio decreases mortality in all massively transfused trauma patients.

Introduction

Uncontrolled hemorrhage is the immediate cause of death in 33-39% of civilian trauma patients (1, 2) and 82-85% of military trauma patients (3, 4). The surgical bleeding that surgeons battle in the operating room is exacerbated by coagulopathy commonly seen in trauma patients. Until recently, coagulopathy after trauma was thought to be primarily caused by a combination of loss of coagulation factors due to hemorrhage, dilution of coagulation factors due to crystalloid resuscitation, and coagulation factor dysfunction due to hypothermia and acidemia (5). While these mechanisms clearly contribute to the coagulopathy of trauma, recent studies indicate that coagulopathy is already present in 25-38% of trauma patients on arrival to the hospital (6-8). Furthermore, patients who arrive at the hospital with traumatic coagulopathy are four times more likely to die (6).

As a result of this improved understanding of the incidence and mechanisms of coagulopathy after trauma, research efforts have focused on determining the ideal hemostatic resuscitation protocol. New evidence suggests that transfusing fresh frozen plasma (FFP) along with packed red blood cells (PRBCs) in a ratio of 1:1 to 1:2 decreases both early (6 and 24 hour) and late (30 day) mortality (9-11). In one study, survival was only 41% in patients who received low ratios of both FFP:PRBC and platelets:PRBC, and increased to 71% in patients who received high ratios of both FFP:PRBC and platelets:PRBC (10). Another study reported that receiving an FFP:PRBC ratio of at least 1:1.5 resulted in a 52% decreased risk of death (11). These studies only included trauma patients who received a massive transfusion, defined as transfusion of 10 units of PRBCs over 24 hours, and did not address whether traumatic coagulopathy was present. It remains unclear which patients are most likely to benefit from transfusion with a high FFP:PRBC ratio. Of the trauma patients who require a massive transfusion, only some have coagulopathy on arrival to the hospital. Moreover, the severity of coagulopathy varies widely among these patients.

Because trauma patients with acute coagulopathy on arrival to the hospital are four times more likely to die, and a high FFP:PRBC ratio has been shown to prevent and treat traumatic coagulopathy, we hypothesized that patients with coagulopathy on arrival to the hospital

may benefit more from transfusion with a high ratio of FFP:PRBC than those who are not coagulopathic. The purpose of this study was to determine if the effect of the ratio of FFP:PRBC on death at 24 hours was modified by a patient's INR on arrival to the hospital.

Materials and Methods

Patient sample, study design, and clinical data

The cohort for this study included 437 massively transfused (transfusion of 10 units of PRBCs within 24 hours of admission) trauma patients. These patients are a subset from an Institutional Review Board approved, retrospective, multicenter study that included adult trauma patients who arrived from the scene and received at least one unit of PRBCs in the Emergency Department (ED) (10). The multicenter trial included patients from sixteen level I trauma centers between July 2005 and June 2006.

Demographic data, clinical data, consisting of admission vital signs, laboratory values, transfusions, and mechanism of injury, and outcome data were collected at each level I trauma center and submitted to a central database at the Department of Epidemiology and Biostatistics at The University of Texas Health Sciences Center in San Antonio, Texas. For our analysis, patients were categorized into quartiles based on their initial International Normalized Ratio (INR) in the ED. The total number of units of FFP and PRBCs transfused were from the first six hours after arrival to the hospital. The ratio of units of FFP transfused to units of PRBCs transfused (FFP:PRBC) were available as both a continuous variable and a dichotomous variable. The dichotomous variable used 1:2 as a cut point for the ratio of FFP:PRBC transfused. For example, a patient who received an FFP:PRBC ratio less than 1:2 received less than 1 unit of FFP for every 2 units of PRBCs. Alternatively, a patient who received an FFP:PRBC ratio greater than or equal to 1:2 received at least 1 unit of FFP for every 2 units of PRBCs. The outcome for this study was 24 hour mortality. The outcome data were available as both a dichotomous variable and as hours from arrival to the hospital until death.

Statistical Analyses

We hypothesized that patients who arrive at the hospital with acute coagulopathy, would have a greater decrease in mortality if given a high FFP:PRBC ratio than patients who arrive without coagulopathy who are also given a high FFP:PRBC ratio. Our hypothesis is an example of an interaction. An interaction occurs when the effect of a risk factor on an outcome is modified by the value of a third variable. In this study, we were interested in determining if the effect of the ratio of FFP:PRBC on 24 hour mortality was modified by a patient's coagulation status on arrival to the hospital.

We tested our hypothesis using two different methods. First, we used contingency tables to compare the effect of receiving a high ratio of FFP:PRBC (1:2) on 24 hour mortality by admission INR. We created nine different cut points for INR (1.1 through 1.9) and used each as a dichotomous variable. For example, consider an INR cut point of 1.5, (<1.5 or ≥1.5). The risk ratio for death at 24 hours assuming transfusion of a high ratio of FFP:PRBC (1:2) was determined for those with an INR <1.5 and for those with an INR ≥1.5. These two risk

ratios were compared and the corresponding p value is for the test of homogeneity that addresses the null hypothesis that the two risk ratios at a particular INR cut point are identical.

The second method we used to test our hypothesis was logistic regression using an interaction term. This was done using three separate analyses. First, a model was constructed in which the FFP:PRBC ratio was continuous and admission INR was categorical (quartiles). In the second model the FFP:PRBC ratio was dichotomous ($<1:2$ or $1:2$) and admission INR was continuous. In the final model both FFP:PRBC and admission INR were continuous. For each of these models we began the analysis by using a cubic spline function to determine if the relationship between the ratio of FFP:PRBC transfused, admission INR, and 24 hour mortality was linear or non-linear. A spline is a statistical tool for producing smooth functions and is ideal for demonstrating a non-linear, complex relationship between a predictor and an outcome. In each model, the p values for the non-linear component of the spline function were not statistically significant, indicating that the relationship between admission INR, ratio of FFP:PRBC transfused, and 24 hour mortality can be modeled as linear. Furthermore, in each model the p value for the interaction term was not statistically significant, indicating that there was no evidence for an interaction between admission INR and ratio of FFP:PRBC transfused. In each of these models we controlled for Injury Severity Score (ISS), Glasgow Coma Score (GCS), and admission base deficit because these factors are well established predictors of mortality in trauma patients. The final logistic regression model included FFP:PRBC as a continuous variable, admission INR quartiles, ISS, GCS, and admission base deficit. The area under the ROC curve for this model was determined and this model was graphed (Figure 2).

A survival analysis was done using hours to death at 24 hours as the outcome. There were 36 patients with missing data for hours from ED to death; this left 401 patients for our survival analysis. The following four groups were compared: INR <1.4 Low Ratio, INR <1.4 , High Ratio, INR 1.4 , Low Ratio, and INR 1.4 , High Ratio. For this analysis, a low FFP:PRBC ratio is $<1:2$ and a high FFP:PRBC ratio is $1:2$. The log-rank test was used to determine if the survival curves differed between the four groups.

Dichotomous variables were compared using the chi-squared test, continuous, normally distributed and nominal variables were compared using one-way analysis of variance, and continuous, non-normally distributed and nominal variables were compared using the Kruskal-Wallis test. STATA/SE 10.1 (College Station, TX) was used for all statistical analyses, which were reviewed by a biostatistician.

Results

The 437 patients in the cohort were categorized into quartiles according to admission INR. There were 110 patients who arrived at the hospital with an INR 1.15 , 109 patients with an INR $1.16-1.35$, 109 patients with an INR $1.36-1.66$, and 109 patients with an INR 1.67 (Table 1). The overall mortality rate at 24 hours was 26%. There were 20 patients (18%) with an INR 1.15 who died, 26 patients (24%) with an INR $1.16-1.35$ who died, 30 patients (28%) with an INR $1.36-1.66$ who died, and 38 (35%) patients with an INR 1.67 who died.

The risk of death at 24 hours increased with increasing INR upon arrival to the hospital (Figure 1). The odds of death at 24 hours were 1.4 times higher for those who arrived with an INR 1.16-1.35 ($p=0.30$, 95% CI 0.7-2.7), 1.7 times higher for those with an INR 1.36-1.66 ($p=0.10$, 95% CI 0.9-3.2), and 2.4 times higher for those with an INR 1.67 ($p=0.006$, 95% CI 1.3-4.5) compared to those with an INR 1.15.

There were 229 patients (52%) in the entire cohort who received an FFP:PRBC ratio of at least 1:2. Fifty-one patients (12%) did not receive FFP within the first 6 hours of arrival. By quartile, 46% of patients with an INR 1.15, 43% of patients with an INR 1.16-1.35, 60% of patients with an INR 1.36-1.66, and 61% of patients with an INR 1.67 received an FFP:PRBC ratio of at least 1:2.

The decrease in mortality with transfusion of a 1:2 FFP:PRBC ratio was similar regardless of INR on arrival to the hospital (Table 2 and Figure 2). There was a 29%-48% decreased risk of death at 24 hours for those who received an FFP:PRBC ratio of at least 1:2 (Table 2).

Trauma patients who arrived at the hospital with acute coagulopathy had a greater risk of death than those without coagulopathy (Figure 1 and Figure 2). However, when we graphed the probability of death according to INR quartile and ratio of FFP:PRBC transfused, while controlling for ISS, GCS score, and admission base deficit, the slopes of the lines for the INR quartile groups were similar (Figure 2). This indicated that as the ratio of FFP:PRBC increased, mortality decreased in a similar fashion between the these groups. However, since those with a higher admission INR started out with a greater probability of death at 24 hours, it took a greater FFP:PRBC ratio to decrease mortality to a similar probability compared to patients with lower INRs. For example, to achieve a 20% probability of death, those in the highest INR quartile would need to receive about 0.75 units of FFP for every one unit of PRBCs transfused, whereas those in the lowest INR quartile would need to receive about 0.5 units of FFP for every one unit of PRBCs transfused. Most importantly, the probability of death at 24 hours decreased in all patients, regardless of admission INR, as the ratio of FFP:PRBC transfused increased.

Our survival analysis indicated that those who arrived at the hospital with an INR <1.4 and who received a high ratio of FFP:PRBC (1:2) had the greatest probability of survival at 24 hours (Figure 3). Interestingly, patients with an INR <1.4 who were given a low ratio of FFP:PRBC had similar survival to those with an INR 1.4 who were given a high ratio of FFP:PRBC (log-rank test $p=0.009$).

Discussion

Our findings suggest that transfusion of a high FFP:PRBC ratio decreases 24 hour mortality in all massively transfused trauma patients, regardless of INR on arrival to the hospital. This is an important finding for two reasons. First, this finding is both novel and contrary to the current belief that only trauma patients who are coagulopathic benefit from hemostatic resuscitation. Second, our results provide evidence to support hemostatic resuscitation in all severely injured patients who require a massive transfusion, regardless of admission INR. Therefore, it is unnecessary to determine whether a patient has an elevated INR before

starting a transfusion protocol using a high FFP:PRBC ratio. However, it is still important to determine how elevated the INR is because those who arrive at the hospital with a higher INR will need a higher FFP:PRBC ratio to decrease mortality since they are starting out with a greater risk of death on arrival than those with a lower INR.

Despite the tremendous recent interest in the diagnosis of traumatic coagulopathy and its treatment using higher FFP:PRBC ratios, severely injured patients are still oftentimes resuscitated according to the Advanced Trauma Life Support (ATLS) protocol, which advises to give crystalloid, and if the patient's vital signs do not improve, to transfuse PRBCs. We now know that the ATLS protocol often results in inadequate resuscitation. Some trauma patients are not seriously injured and may not need excessive crystalloid resuscitation (or any resuscitation at all), while others are critically injured, have coagulopathy, and need an immediate blood component-based hemostatic resuscitation protocol. Not only are the current resuscitation protocols less effective than hemostatic resuscitation protocols at decreasing mortality, in addition, clinicians typically do not start these protocols unless certain criteria are met, namely changes in vital signs or laboratory results.

The diagnosis of traumatic coagulopathy relies upon the measurement of prothrombin time (PT), partial thromboplastin time (PTT), and INR. These laboratory tests take approximately 25 minutes to complete on a functional coagulation analyzer. Overall, it can take 45 minutes to 1 hour before these results are available to the clinician in most centers. It is usually not until these laboratory results are available that the clinician evaluates them and decides whether to transfuse FFP. Therefore, when FFP is transfused, it is typically transfused much later than PRBCs. Our results demonstrate that the transfusion strategy used within the first six hours of arrival to the hospital affects mortality at 24 hours in massively transfused trauma patients. The sooner a clinician recognizes the need to transfuse FFP, the more likely that patient is to receive the necessary ratio of FFP:PRBC. Since all massively transfused trauma patients experience a mortality benefit from hemostatic resuscitation, it is unnecessary to wait for laboratory results before deciding to transfuse FFP.

Several investigators have attempted to address this delay in the transfusion of FFP by using simple scoring systems to predict which patients are likely to need massive transfusion (12-16), and are therefore more likely to benefit from hemostatic resuscitation, and by using pre-thawed refrigerated plasma available in the ED (17). Both of these concepts are important. If clinicians can identify which patients are likely to need a massive transfusion, then a hemostatic resuscitation protocol can be started for these patients without delay. In addition, once these patients are identified, if pre-thawed FFP is available in the ED, this would further decrease delay in transfusion of FFP.

The mechanism by which transfusion of a high FFP:PRBC ratio decreases mortality in all massively transfused trauma patients regardless of admission INR remains unknown. There are several possible reasons for our findings, including the beneficial effects of de novo plasma, reduced crystalloid usage, and the prevention of secondary, acquired coagulopathy. Prospective studies to determine the mechanisms underlying the mortality benefit of hemostatic resuscitation are currently underway at our center and others.

There are several limitations to this study. First, and most importantly, we do not have data on the timing of transfusion of each of the blood components. Some patients may have received a 1:2 FFP:PRBC ratio upon arrival to the ED. However, others may have received many units of PRBCs within the first several hours and later received FFP in quantities sufficient to end up with a final FFP:PRBC ratio of 1:2. These two management strategies are quite different and it is unknown if they are equally efficacious. Second, survival bias may be present because patients with severe hemorrhage are likely to die early and may die before they have the chance to receive FFP. In centers where thawed plasma is available in the ED, this bias would be mitigated because every patient would have an equal chance of receiving a high FFP:PRBC ratio. Using the FFP:PRBC transfusion ratios from the first 6 hours after admission, rather than a longer time frame, may have decreased both the timing of transfusion bias and survival bias. The longer the time frame to calculate the transfusion ratios, the more time those who survived longer had to reach a high FFP:PRBC ratio. Finally, this is a retrospective study and many unmeasured variables that may also affect survival were not controlled for in our analyses.

In conclusion, we found that transfusion of a high FFP:PRBC ratio is associated with decreased mortality in all massively transfused trauma patients, regardless of admission INR. Prospective clinical studies are needed to validate these findings and determine the mechanism through which a high FFP:PRBC ratio decreases mortality.

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Figure 1.

Proportion of survivors and non-survivors at 24 hours by International Normalized Ratio (INR) Quartile on arrival to the hospital.

Figure 2. Relationship between the ratio of FFP:PRBC transfused and the probability of death at 24 hours by Admission INR Quartile

This logistic regression model also controls for ISS, GCS, and admission base deficit. Area under the ROC curve=0.79. FFP, fresh frozen plasma; PRBCs, packed red blood cells

Figure 3. Survival analysis demonstrating the probability of survival over the first 24 hours according to admission INR and the ratio of FFP:PRBCs transfused

High Ratio is FFP:PRBC 1:2 and Low Ratio is FFP:PRBC <1.2 (log-rank test $p=0.009$).

FFP, fresh frozen plasma; PRBCs, packed red blood cells

Table 1
Baseline Characteristics of 437 Massively Transfused Trauma Patients by Admission INR Quartile

Characteristic	INR 1.15 (n= 110)	INR 1.16-1.35 (n=109)	INR 1.36-1.66 (n=109)	INR 1.67 (n=109)	p value
Age	45 ± 18	42 ± 18	37 ± 18	38 ± 17	<0.001
Male	68%	71%	81%	73%	0.18
Mechanism of Injury					
Penetrating	33%	33%	38%	31%	0.66
Blunt	67%	66%	62%	69%	
Injury Severity Score	30 ± 17	31 ± 15	33 ± 16	36 ± 16	0.08
Glasgow Coma Score	12 ± 5	10 ± 5	9 ± 6	7 ± 5	<0.001
PT	13 ± 2	15 ± 3	17 ± 2	24 ± 6	<0.001
PTT	26 ± 7	31 ± 10	36 ± 11	69 ± 42	<0.001
Platelets	259 ± 81	231 ± 92	200 ± 79	149 ± 72	<0.001
Hemoglobin	12 ± 2	11 ± 2	11 ± 2	9 ± 3	<0.001
Base Deficit	-8 ± 6	-10 ± 6	-10 ± 6	-13 ± 7	<0.001
Systolic Blood Pressure	110 ± 30	108 ± 31	97 ± 27	94 ± 31	<0.001
Heart Rate	110 ± 27	114 ± 26	116 ± 30	114 ± 29	0.34
Respiratory Rate	21 ± 8	22 ± 9	22 ± 14	22 ± 8	0.71
Temperature	36.1 ± 0.8	35.8 ± 1.1	36.0 ± 1.5	35.9 ± 1.0	0.36
Units FFP transfused ³	7 ± 7	7 ± 7	9 ± 7	10 ± 7	<0.001
Units PRBCs transfused ³	15 ± 11	15 ± 11	17 ± 12	17 ± 10	0.06

¹ Mean ± Standard Deviation

² One patient (1%) with missing mechanism of injury data in this INR quartile

³ Number of units of FFP or PRBCs transfused within the first 24 hours of admission

Table 2

Risk of Death at 24 Hours by Admission INR and Ratio of FFP:PRBCs Transfused

1:2 Ratio of FFP:PRBC			
INR ^I	n	Risk Ratio	p value
<1.1	43	0.60	0.8
1.1	394	0.69	
<1.2	107	0.61	0.8
1.2	330	0.68	
<1.3	166	0.61	0.8
1.3	271	0.69	
<1.4	216	0.52	0.4
1.4	221	0.70	
<1.5	265	0.64	0.8
1.5	172	0.69	
<1.6	294	0.63	0.7
1.6	143	0.71	
<1.7	326	0.65	0.9
1.7	111	0.68	
<1.8	344	0.67	0.8
1.8	93	0.61	
<1.9	355	0.64	0.8
1.9	82	0.71	
<2.0	371	0.64	0.8
2.0	66	0.71	

^I Admission INR