ORIGINAL ARTICLE

Implementation of a massive transfusion protocol: A single trauma center experience from South Korea

Min A Lee, M.D.,[1] HyeMin Park, M.D.,[3] Byungchul Yu, M.D.,[1] Kang Kook Choi, M.D.,[1] Youngeun Park, M.D.,[2] Gil Jae Lee, M.D.[1]

[1]Department of Traumatology, College of Medicine Gachon University, Incheon-*South of Korea*
[2]Department of Trauma Surgery, Gachon University Gil Medical Center, Incheon-*South of Korea*
[3]Department of Internal Medicine, Gachon University Gil Medical Center, Incheon-*South of Korea*

ABSTRACT

BACKGROUND: Massive transfusion (MT) is traditionally defined as transfusion of more than 10 units of red blood cells (RBCs) within the first 24 h after admission. The aim of this study is to analyze the trend of MT in regional trauma center including ratio of fresh frozen plasma (FFP) and packed RBC.

METHODS: Retrospective data were driven from 2014 to 2016. A total of 185 patients who received more than 10 packed RBC units within the first 24 h after admission were included in the study. We analyzed transfusion requirements for each time interval 4 h and 24 h after admission. Moreover, we compared transfusion characteristics between survival and non-survival group, between high FFP:RBC group (≥1: 2) and low FFP:RBC group (<1: 2), and between the first half and latter half period.

RESULTS: There was a trend for improvement in the FFP:RBC ratio after applying the MT protocol. The FFP:RBC ratio increased from 1:1.7 to 1:1.4 within 24 h after arrival. The time to first transfusion was shortened (137–106 min). Mortality was lower in high FFP:RBC group than that of low FFP:RBC group.

CONCLUSION: In our study, the MT protocol improved the FFP:RBC ratio. A higher FFP:RBC ratio also led to an improvement in the mortality rate in MT patients.

Keywords: Massive transfusion; protocol; trauma.

INTRODUCTION

Trauma is the second leading cause of death and the second most frequent cause of massive transfusion (MT) worldwide.[1] In 2010, hemorrhage-related deaths accounted for approximately 40% of deaths due to trauma.[2] Rapid transfusion of an appropriate amount of blood is essential for reducing death from hemorrhage, and a MT protocol can be helpful as a way to achieve this goal.[3–6]

MT was traditionally defined as the transfusion of 10 or more units of packed red blood cells (RBCs) within the first 24 h after admission.[7] Since the 1990s, studies have investigated the importance of rapid transfusion after admission, as well as the use of more balanced transfusion units. Early and aggressive transfusion with a high ratio of fresh frozen plasma (FFP) or platelets to RBCs can reportedly decrease mortality among MT patients.[8] Although increasing the plasma ratio in MT improves coagulopathy, there are various opinions about the appropriate ratio of plasma to packed RBCs and the patient-specific use of blood components based on coagulation (conventional and/or viscoelastic) tests.[9] Furthermore, the relationship between coagulopathy and mortality is complex and difficult to prove.[10,11] The previous studies have proposed an ideal FFP:RBC ratio of 1:1.[8,12–18] However, other studies have reported that a high

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Address for correspondence: Gil Jae Lee, M.D.
Namdong-daero 774 beon-gil, Namdong-gu 21565 Incheon - Korea-South
Tel: 82-32-460-3010 E-mail: nonajugi@gilhospital.com

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FFP:RBC ratio did not influence the mortality of trauma patients.[18,19]

The purpose of this study was to review our experiences of performing MT for severely injured patients with the objective of evaluating the impact of the FFP-to-RBC ratio on coagulopathy and mortality.

MATERIALS AND METHODS

The study was performed in the trauma center of the Gachon University Gil Hospital in South Korea. This study was approved by the local ethics committee (GFIRB2021-137).

In 2012, the Ministry of Health and Welfare in South Korea started to set up a national trauma system. The main purpose was to establish a network of regional trauma centers. Our trauma center is the first trauma center established in South Korea and is properly equipped based on the standards of the United States level I trauma centers.

Using electronic medical records, retrospective data from January 2014 to December 2016 were obtained from the authors' regional trauma center. The inclusion criteria were patients who received more than 10 packs of RBC transfusion within 24 h. Patients younger than 16 years were excluded from this analysis. We used patients' basic characteristics, including age, sex, mechanism of injury, and hospital admission data, including the Injury Severity Score (ISS), Abbreviated Injury Scale, the time interval from trauma or admission to transfusion, and physiological measurements (body temperature, mean arterial blood pressure, heart rate, respiratory rate, oxygenation, arterial pH, hemoglobin, hematocrit, lactate, international normalized ration (INR), systolic and diastolic blood pressure, and the Glasgow Coma Scale [GCS]). We also used transfusion-related intervention information, which included packed RBCs, FFP, and platelets, along with the time taken for these units to be transfused within the first 4 h and 24 h after admission (specifically, 0–4 h, and within 24 h). Our trauma data system automatically monitored patients' transfusion status 4 and 24 h after being hospitalized for quality control.

To analyze the effect of the FFP:RBC ratio, patients were classified into two groups. At our institution, FFP cannot be transfused as fast as RBCs. Type O RBCs can be transfused as soon as they are requested, but FFP takes about 1 h, as it takes time to dissolve the blood. Therefore, it is not easy to achieve a high RBC:FFP ratio in the early phase. Referring to the literature, cases where the FFP:RBC ratio was greater than 1:1.5 were defined as the high FFP group, and those with a ratio lower than 1:1.5 were assigned to the low FFP group.[20–22] Patients with a ratio of 0, who received only RBCs and no FFP, were classified as belonging to the low FFP group.

Since the establishment of the trauma center in 2014, efforts have been made to establish various protocols within the institution. The MT protocol was established through a multidisciplinary conference (including trauma department staff, emergency department staff, a laboratory medicine physician, and a medical laboratory scientist) held in June 2015. Therefore, the difference between the periods before and after the MT protocol was established (January 2014-June 2015 vs. July 2015-December 2016) was also investigated.

Basic demographic data were analyzed using the Fisher's exact test for categorical variables and the Mann-Whitney U-test for continuous variables. Statistical significance was accepted at $p<0.05$. Transfusion characteristics were compared between the survival and non-survival groups and between the high FFP group (≥1:1.5) and the low FFP group (<1:1.5).

RESULTS

In total, 9332 patients were admitted over a 3-year period. Transfusions were administered to 978 patients, and 185

Table 1. Baseline demographic characteristics of patients

Characteristic	n	%	Mean±SD
N	185		
Age (years)			52.3±17.7
Males	136	73.5	
Injury mechanism			
Blunt injury	165	89.2	
Penetrating injury	18	9.7	
SBP at admission (mmHg)			102.7±41.1
Respiratory rate/min at admission			21.4±5.8
Heart rate (bpm) at admission			104.2±27.5
Body temperature at admission (°C)			36.0±1.0
GCS at admission			9.4±5.1
pH			7.3±0.2
INR			1.8±1.5
Hemoglobin			10.5±2.4
Hematocrit			31±6.7
Base excess			-10.5±6.5
Lactate			6.2±3.6
Final ISS*			28.8±11.9
Transfusion requirements within 24 h after admission			
RBC			21.1±16
FFP			13±11.6
Platelets			6.1±7.1
Immediate surgical treatment	133	71.9	
Mortality	90	48.6	

GCS: Glasgow Coma Scale; INR: International normalized ratio; ISS: Injury Severity Score; RBC: Red blood cell; FFP: Fresh frozen plasms; SBP: Systolic blood pressure; SD: Standard deviation.

(18.9%) patients received MT, which was defined as receiving more than 10 units of packed RBCs within 24 h after admission. Basic demographic data are shown in Table 1. A total of 185 patients who received transfusion with 10 or more units of packed RBCs within the first 24 h after admission were included in this study. The patients' average age was 52.3 years, and 136 (73.5%) patients were men. In this study, 89.2% of patients were admitted due to blunt injuries. The mortality rate-defined as the proportion of trauma-related deaths in the hospital-among patients treated with 10 or more transfused RBC units was 48.5%.

The number of transfusions required within 4, 4–24, and 24 h and the average FFP:RBC ratio for each time interval were reported (Table 2). The FFP:RBC transfusion ratio (range) was 1.5 (0–2.1) within 4 h, 1.0 (0.6–1.7) within 4–24 h, and 1.5 (1.2–2.1) within 24 h.

The characteristics of the survival (n=90) and non-survival (n=95) groups were also compared (Table 3). The survival group had significantly higher hemoglobin, hematocrit, pH, base excess, and GCS scores on admission and lower INR, lactate, and ISS. The average time interval from admission to

Table 2. Transfusion requirements at 4 hours and 24 hours after admission (median, IQR)

Characteristic		Transfusion requirements	Average FFP:RBC ratio for each time interval
Transfusion within 4 hours	Packed RBCs	9 (5–14)	1.5 (0–2.1)
	FFP	4 (0–7)	
	Platelets	0 (0–0)	
	RBC:FFP	2.3: 1	
Transfusion within 4 to 24 hours	Packed RBCs	8 (4–13)	1.0 (0.6–1.7)
	FFP	5 (3–11)	
	Platelets	2 (0–10)	
	RBC:FFP:Platelts	1.6: 1: 0.4	
Transfusion within 24 hours	Packed RBCs	16 (12–24)	1.5 (1.2–2.1)
	FFP	10 (6–17)	
	Platelets	2 (0–10)	
	RBC:FFP:Platelts	1.6: 1: 0.2	

IQR: Interquartile range; RBC: Red blood cell; FFP: Fresh frozen plasma.

Table 3. Comparison of the characteristics of patients according to survival outcomes

Characteristic	Non-survival group (n=90)	Survival group (n=95)	p-value
Age	53 (42–67)	54 (37–64)	0.348
Men (%)	56 (62.2)	80 (85.2)	0.001
Hemoglobin	9.7 (8.1–11.2)	11.5 (9.9–12.5)	<0.001
Hematocrit	28.9 (24.4–33.6)	33.1 (28.7–36.2)	<0.001
pH	7.20 (7.07–7.32)	7.34 (7.26–7.39)	<0.001
INR	1.6 (1.3–2.0)	1.3 (1.2–1.5)	<0.001
Base excess	-13.6 (-18.3–-9.5)	-7.9 (-10.7–-4.4)	<0.001
Lactate	7.9 (5.1–10.9)	4.4 (2.7–5.6)	<0.001
Admission GCS	4 (3–8)	15 (11–15)	<0.001
Final ISS*	29 (25–38)	25 (17–33)	0.001
Interval from trauma to transfusion (min)	120 (66–215)	110 (73–202)	0.650
Interval from admission to transfusion (min)	29 (21–99)	35 (22–86)	0.585
FFP-RBC ratio within 4 hours	1.3 (0–2.0)	1.7 (0.9–2.3)	
FFP-RBC ratio within 24 hours	1.5 (1.1–2.2)	1.6 (1.3–2.1)	0.229

INR: International normalized ratio; GCS: Glasgow Coma Scale; ISS: Injury Severity Score; FFP: Fresh frozen plasma; RBC: Red blood cell.

Table 4. Comparison of characteristics of the high-FFP group (FFP:RBC≥1:1.5 within 24 hours) and the low-FFP group (FFP:RBC<1:1.5 within 24 hours)

Characteristic	High FFP group (n=89)	Low-FFP group (n=96)	p-value
Age	53 (42–66)	54 (38–64)	0.959
Sex (male)	62 (69.7%)	74 (77.1%)	0.317
Hemoglobin	10.7 (9.3–12.0)	10.7 (9.3–12.0)	0.379
Hematocrit	30.3 (26.7–35.3)	31.3 (26.8–35.7)	0.384
pH	7.25 (7.15–7.36)	7.29 (7.20–7.37)	0.164
INR	1.5 (1.3–1.8)	1.4 (1.3–1.7)	0.499
Base excess	-11.7 (-16.7–-8.3)	-8.5 (-13.5–-5.0)	0.003
Lactate	6.0 (3.7–8.6)	5.1 (3.6–7.5)	0.176
Admission GCS	7 (3–15)	13 (4–15)	0.116
Final ISS*	29 (24–38)	26 (18–34)	0.031
TRISS			
ICU stay	8 (3–31)	8 (3–21)	0.459
Hospital day	12 (1–52)	14 (4–47)	0.381
Interval from trauma to transfusion (min)	88 (64–200)	138 (76–209)	0.032
Interval from admission to transfusion (min)	26 (19–56)	44 (24–164)	0.001
Mortality (%)	47 (52.8%)	43 (44.8%)	0.305

FFP: Fresh frozen plasma; RBC: Red blood cell; INR: International normalized ratio; GCS: Glasgow Coma Scale; ISS: Injury Severity Score; TRISS: Trauma and Injury Severity Score; ICU: Intensive care unit.

transfusion and from trauma to transfusion was not statistically different, and neither was the FFP:RBC transfusion ratio.

The characteristics of the high FFP group and the low FFP group were compared (Table 4). In the high FFP group, base excess was lower (−11.7 vs. −8.5, p=0.003) and the ISS score was higher (29 vs. 26, p=0.031). The interval from admission to transfusion was shorter in the high FFP group (26 min vs. 44 min, p=0.001), while the mortality rate was not significantly different between the two groups (52.8% vs. 44.8%, p=0.305).

The results from January 2014 to June 2015 and from July 2015 to December 2016 were compared (Table 5). There was no significant difference in other patient-related indicators during the two periods, but the ISS was higher (26 vs. 29, p=0.05) in the second period. Compared with patients in the first period, patients in the second period received MT faster after trauma (137 min vs. 106 min, p=0.03). Moreover, the FFP:RBC ratio was higher (1.7 vs. 1.4, p=0.004) in the second period. The mortality rate decreased from 50.5% in the first half period to 46.8% in the second period, but this difference was not statistically significant.

DISCUSSION

MT occurs in 3–5% of all civilian and 8–10% of all military trauma patients.[23,24] Although MT is used in a relatively small proportion of trauma patients, mortality due to hemorrhage within these patients occurs early (in the first 6 h after arrival) and is frequent (40%).[13,25–27] Furthermore, these MT patients consume more than 70% of all blood transfused to trauma patients.[28]

Some differences among countries should be considered regarding trauma patients and the trauma care system. Blunt injuries account for the majority of all injuries in Korea. The percentage of patients with blunt trauma was 89.2% in this study, which is similar to that reported in studies published in Japan (80–100%).[29] However, this proportion is much higher than has been reported in the US studies, where blunt trauma accounts for 40–60% of trauma cases.[7,13] In general, blunt trauma patients have different injury patterns from those of patients with penetrating trauma.[30] The major cause of early mortality in patients with penetrating trauma is trunk hemorrhage.[26] Patients with penetrating trauma are more likely to require massive blood transfusions than those with blunt trauma.[31] Rowell et al.[32] found that the use of high plasma:RBC ratios during MT may be more beneficial for patients with penetrating injuries than for patients with blunt injuries.

Early and aggressive plasma transfusion is important in patients with critical hemorrhagic trauma. Zink et al.[33] reported that a higher ratio of FFP:RBC transfusion within the first 6 h improved both 6 h and in-hospital mortality. No consensus exists regarding the optimal FFP:RBC ratio; however, many authors agree that a ratio of 1:1–1:2 is associated with lower mortality. In the PROPPR randomized trial, the 24

Table 5. Comparison of characteristics of the periods before and after adoption of the massive transfusion protocol

Characteristic	Before the protocol (n=91) (January 2014 to June 2015)	After the protocol (n=94) (July 2015 to December 2016)	p-value
Age	53 (35–66)	53 (42–63)	0.964
Sex (male)	64 (47.1%)	72 (52.9%)	0.405
Hemoglobin	10.2 (9.2–12.0)	10.7 (9.1–12.0)	0.872
Hematocrit	30.3 (26.8–35.3)	31.2 (26.7–35.6)	0.989
pH	7.28 (7.15–7.36)	7.29 (7.19–7.37)	0.581
INR	1.4 (1.3–1.7)	1.4 (1.2–1.8)	0.327
Base excess	-10.7 (-15.5–-6.8)	-9.5 (-14.2–-5.6)	0.277
Lactate	5.1 (3.4–7.8)	5.6 (4.0–8.7)	0.282
Admission GCS	10 (3–14)	11 (4–15)	0.580
Final ISS*	26 (18–34)	29 (24–38)	0.050
TRISS			
ICU stay	8 (3–16)	11 (3–38)	0.065
Hospital day	12 (2–47)	16 (1–52)	0.749
Interval from trauma to transfusion (min)	137 (73–250)	106 (64–199)	0.030
Interval from admission to transfusion (min)	29 (22–111)	30 (22–86)	0.819
FFP-RBC ratio within 4 hours	1.6 (0–2.3)	1.4 (0–2.0)	0.302
FFP-RBC ratio within 24 hours	1.7 (1.3–3.0)	1.4 (1.1–1.9)	0.004
Mortality (%)	46 (50.5%)	44 (46.8%)	0.660

INR: International normalized ratio; GCS: Glasgow Coma Scale; ISS: Injury Severity Score; ICU: Intensive care unit; FFP: Fresh frozen plasma; RBC: Red blood cell.

h mortality rate was 43% in the 1:1:1 FFP:platelet:RBC group compared with 58% in the 1:1:2 FFP:platelet:RBC group.[34] Sperry et al.[35] reported that an FFP:RBC ratio higher than 1:1.5 was associated with a lower risk of mortality in a multicenter prospective cohort study. In a multicenter study, the high FFP group (>1:1.5 FFP:RBC) showed a lower mortality rate than the low FFP group (47.6% vs. 86.6%, p=0.03).[22] We conducted a retrospective study of MT at a single trauma center. There was a trend for improvement in the FFP:RBC ratio after applying the MT protocol. The FFP:RBC ratio increased from 1:1.7 to 1:1.4 within 24 h after arrival.

Coagulopathy is common in bleeding trauma patients; therefore, it is important to monitor coagulation while applying the MT protocol. For coagulation monitoring, the viscoelastic method (VEM) is recommended in addition to traditional laboratory data such as the prothrombin time, platelet count, and international normalized ratio. VEM provides a quick assessment of hemostasis to assist in clinical decision-making.[9] An MT protocol can improve the mortality rate of severe bleeding patients by minimizing hemorrhage and coagulopathy through transfusion of predetermined blood components.[24,36] Dente et al.[37] reported a reduction in the 24 h mortality (36% vs. 17%, p=0.008) after applying an MT protocol. Many authors have demonstrated that providing blood products in an organized and predefined fashion is associated with improved survival in severely injured trauma patients.[13,17,38] Cotton et al.[39] demonstrated that an exsanguination protocol, delivered in an aggressive and predefined manner, significantly reduced the odds of mortality as well as overall blood product consumption. The increase in the MT protocol adherence rate by the trauma teams at our center was accompanied by improvements in time to transfusion, blood component ratios, and the mortality rate. The overall mortality rate improved from 50.5% to 46.8%. The time to first transfusion was shortened and the FFP:RBC ratio within 24 h was improved. However, there was no improvement in the proportion of patients who received FFP transfusion within 4 h.

Rapid transfusion with high FFP or platelet ratios may lead to lower mortality in patients who receive MT.[40] However, some studies have suggested that the effect of a higher FFP:RBC ratio on lower mortality was overstated and could be attributed to survival bias.[19] Hypothermia and unheated blood transfusion can adversely affect acidosis and coagulopathy, increasing the mortality of severe trauma patients.[41] Our center included a heated blood transfusion in the MT protocol; however, it was not always completed in all cases, meaning that the findings might have been affected by survival bias.

Our study has some limitations. First, the study was limited due to the short supply and infrequent use of plasma and platelets. The MT protocol usually includes the use of tranexamic acid; however, at our institution, this was not implemented in some patients. This study focused on the ratio of blood components, instead of general management of bleeding trauma patients such as tranexamic acid. Second, this was a retrospective study analyzing data from a single institution. In addition, some aspects of applying the MT protocol were not straightforward due to the variety of trauma team members and the need to train new personnel.

Conclusion

In our study, the MT protocol improved the FFP:RBC ratio. A higher FFP:RBC ratio also led to an improvement in the mortality rate in MT patients. Further research should investigate more widely adopted MT protocols and conduct prospective studies in diverse global settings to clarify the effect of the optimal ratio of blood components for severe trauma patients.

Ethics Committee Approval: This study was approved by the local ethics committee (No: GFIRB2021-137).

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ORİJİNAL ÇALIŞMA - *ÖZ*

Masif transfüzyon protokolünün uygulanması: Güney Kore'den tek bir travma merkezi deneyimi

Dr. Min A Lee,[1] Dr. HyeMin Park,[3] Dr. Byungchul Yu,[1] Dr. Kang Kook Choi,[1] Dr. Youngeun Park,[2] Dr. Gil Jae Lee[1]

[1]Gachon Üniversitesi Tıp Fakültesi, Travmatoloji Bölümü, Incheon-*Güney Kore*
[2]Gachon Üniversitesi Gil Tıp Merkezi, Travma Cerrahisi Bölümü, Incheon-*Güney Kore*
[3]Gachon Üniversitesi Gil Tıp Merkezi, İç Hastalıkları Anabilim Dalı, Incheon-*Güney Kore*

AMAÇ: Masif transfüzyon (MT), geleneksel olarak, hasta kabülünden sonraki ilk 24 saat içinde 10 üniteden fazla eritrosit (RBC) transfüzyonu olarak tanımlanır. Bu çalışmanın amacı, bölgesel bir travma merkezinde taze donmuş plazma (TDP) ve eritrosit oranı dahil olmak üzere masif transfüzyon (MT) eğilimini analiz etmektir.
GEREÇ VE YÖNTEM: Geriye dönük veriler 2014'ten 2016'kadar tarandı. Başvurudan sonraki ilk 24 saat içinde 10 üzeri eritrosit ünitesi alan toplam 185 hasta çalışmaya alındı. Başvurudan sonra her bir 4 saatlik dilimlerde ve 24 saat sonra transfüzyon gereksinimleri analiz edildi. Hayatta kalan ve hayatta kalmayan grup arasında, yüksek TDP: eritrosit grubu (≥1: 2) ve düşük TDP: eritrosit grubu (<1: 2) arasında ve ilk yarı ile ikinci yarı dönem arasındaki transfüzyon özellikleri karşılaştırıldı.
BULGULAR: Masif transfüszyon protokolünü uyguladıktan sonra FFP: eritrosit oranında bir iyileşme eğilimi vardı. FFP: eritrosit oranı, bavurudan sonraki 24 saat içinde 1:1.7'den 1:1.4'e yükselmişti. İlk transfüzyona kadar geçen süre kısalmıştı (137 dakikadan 106 dakikaya). Mortalite, yüksek TDP:eritrosit grubunda, düşük TDP: eritrosit grubuna göre daha düşüktü.
TARTIŞMA: Çalışmamızda, MT protokolü FFP: eritrosit oranını iyileştirmiştir. Daha yüksek bir TDP:eritrosit oranı da MT hastalarında ölüm oranında bir iyileşmeye yol açmıştır.
Anahtar sözcükler: Masif transfüzyon; protokol; travma.

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