Use of a Massive Transfusion Protocol in Nontrauma Patients: Activate Away

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BACKGROUND: Recently, concern has been raised that the use of massive transfusion protocols (MTPs) in nontrauma (ie, general medical/surgical [GMS]) patients might be inefficient due to protocol overactivation (activation in patients who do not ultimately receive massive transfusion). The current study was designed to investigate whether an MTP could be used effectively in GMS patients without detrimentally impacting resource allocation.

STUDY DESIGN: A retrospective analysis was performed using institutional blood bank records from 2011. Trauma and GMS patients who had ≥10 U packed RBC issued to them in a single release were identified and categorized into MTP and no MTP (nMTP) cohorts.

RESULTS: The protocol was overactivated in 53.8% of GMS patients. Activation of the MTP accelerated the delivery of component products for all patients. In GMS MTP patients, fresh frozen plasma units were issued a median of 7 minutes earlier than in GMS nMTP patients (MTP: median 1.0 minute; interquartile range [IQR] 0.0 to 2.0 minutes vs nMTP: median 8.0 minutes; IQR 0.0 to 37.5 minutes; $p = 0.009$), and platelet units were issued 17 minutes earlier (MTP: median 7.0 minutes; IQR 0.0 to 15.0 minutes vs nMTP: median 24.0 minutes; IQR 9.0 to 96.0 minutes; $p = 0.010$). In GMS MTP patients, there was a statistically significant increase in the percentage of platelet units wasted (MTP 12.8% vs nMTP 8.1%; $p = 0.046$). This increase was also seen in trauma MTP patients (MTP 12.2% vs nMTP 4.0%; $p < 0.001$).

CONCLUSIONS: Despite finding that our MTP is overactivated in GMS patients, we could identify no unique disadvantages to its use with respect to resource allocation. In fact, a potential advantage to MTP activation exists, as products are issued more quickly with less variability. Our findings of increased platelet waste were not unique to GMS patients and should be used as a metric for quality improvement. (J Am Coll Surg 2013;216:1103−1109. © 2013 by the American College of Surgeons)

In trauma patients requiring massive transfusion (defined as the delivery of ≥10 U packed red blood cell [PRBC] in a 24-hour period), there is a growing body of evidence emphasizing the importance of earlier, more aggressive transfusion of fresh frozen plasma (FFP) and platelets (PLT).[1-8] Referred to as hemostatic resuscitation, this transfusion strategy has been recommended to prevent hemodilution and to restore normal coagulation function, potentially providing better control of hemorrhage and a reduction in complications. As a result, many institutions have implemented massive transfusion protocols (MTPs) designed to efficiently deliver predesignated ratios of FFP and PLT.

Recent literature evaluating the effectiveness of these protocols in trauma patients has demonstrated an association with decreased morbidity and mortality.[7,9-13] Considerably fewer studies, however, have investigated the use of these protocols outside of the trauma setting. In gastrointestinal hemorrhage, the implementation of an MTP has been associated with decreased PRBC transfusion without increased incidence of adverse outcomes.[14] Massive transfusion protocols have also been developed for use in obstetrical bleeding.[15] In postpartum hemorrhage, MTP activation has been associated with early access to products and favorable hematologic indices.[16]

Recently, however, there has been concern that the use of MTPs in nontrauma (general medical/surgical [GMS])

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Abbreviations and Acronyms

FFP = fresh frozen plasma
GMS = general medical/surgical
MTP = massive transfusion protocol
PLT = platelet
PRBC = packed red blood cells

patients can be inefficient due to their overactivation in patients who do not ultimately require massive transfusion.[17] Given the paucity of data on massive transfusion outside of the trauma setting, the current study was designed to investigate the hypothesis that an MTP could be used effectively in GMS patients without detrimentally impacting resource allocation.

METHODS

A retrospective analysis was performed using blood bank emergency release records at the University of Pittsburgh Medical Center and the Institute for Transfusion Medicine from January 1, 2011 to December 31, 2011 after approval of the University of Pittsburgh Medical Center Quality Assurance committee (QIRB878). An emergency release was defined as a request for the immediate release of PRBCs, which might have included the issuing of uncrossmatched blood products if there was insufficient time to obtain a patient sample and/or perform a crossmatch. At our institution, in response to a patient with massive hemorrhage, a physician in any location of the hospital has the option to order $\geq$10 U emergent PRBC in a 24-hour period with or without activation of the MTP. The FFP and PLT units are provided automatically in predetermined ratios after MTP activation, but must be specifically ordered when the protocol is not activated. At the time of data collection, the University of Pittsburgh Medical Center MTP called for transfusion of PRBCs, FFP, and PLT in a ratio of 1:1:0.5.

Patients who had $\geq$10 U PRBC issued to them in a single release were identified from the emergency release records and represented the inclusion criteria for the current study. Using information from the electronic medical records, patients with an issue of $\geq$10 U PRBC were categorized based on whether the MTP was activated during their care. If patients were initially resuscitated without activation of the MTP, but subsequently had MTP activation, they were classified in the MTP cohort and the analysis began at the time of MTP activation. Trauma and GMS patients were classified based on the indication for the emergent release of products, as detailed in the medical record. Patient demographic information was also obtained from these records.

A prospectively collected blood bank transfusion database was used to determine the frequency and timing for all products issued, as well as the number of products transfused and wasted in the 24 hours, including and after the emergency release of the PRBC units. Importantly, not all patients who had $\geq$10 U PRBCs issued to them were transfused with all of these units, as some of these units might have been returned. Massive transfusion was defined as receiving $\geq$10 U PRBC in 24 hours.

Only patients who met criteria for massive transfusion as defined here were included in calculations of mean transfused FFP:PRBC and PLT:PRBC ratios. Ratios were calculated at the end of the 24-hour period. Pooled whole blood–derived PLT units were converted to individual PLT units for calculations (1 pooled whole blood–derived PLT unit or 1 apheresis PLT unit = 5 individual PLT units), and all PLT values and ratios are representative of individual PLT units.

The time to return a given blood product was determined by subtracting the time a unit was returned from the time the product was issued. Patients were excluded from these analyses if the blood products were either not issued or if they were transfused with all of the issued units. The "time to issue FFP" and the "time to issue PLT" were measured by calculating the difference in time from the issue of the first FFP or PLT unit to the issue of the 10 emergent PRBC units. The time to issue was used as opposed to the "time to transfusion" because the exact time of administration was unavailable in the existing dataset.

Data are summarized as mean $\pm$ SD, median (interquartile range), or percentage (%). Mann-Whitney *U* tests were used to compare continuous variables, and chi-square or Fischer's exact tests were used for categorical variables. Statistical analyses were performed using SPSS software, version 19 (SPSS, Inc). Statistical significance was defined as $p < 0.05$.

RESULTS

One hundred and sixty-four patients met entry criteria and constituted the study group. For each of these patients, $\geq$10 U emergent, uncrossmatched PRBC were issued in a single release of products. Of these patients, 100 (61%) sustained traumatic injuries and 64 (39%) were issued blood for nontraumatic indications. The indications for GMS emergency release of blood included gastrointestinal bleeding (n = 21 [32.8%]), medical bleeding for other reasons (n = 6 [9.4%]), postsurgical/procedural complications (n = 18 [28.1%]), vascular emergencies (n = 18 [28.1%]), and cerebral hemorrhage (n = 1 [1.6%]). Prospectively collected blood bank data indicated a total of 65 MTP activations during the study

Table 1. Demographic Characteristics of General Medical/Surgical Patients

	MTP (n = 26)	nMTP (n = 38)	p Value
Age, y, mean ± SD	57.9 ± 19.8	64.6 ± 16.4	0.101
Male, n (%)	18 (69.2)	28 (73.7)	0.697
Received MT, n (%)	12 (46.2)	19 (50.0)	0.762
24-h mortality, n (%)	8 (30.8)	6 (15.8)	0.155
30-d mortality, n (%)	13 (50.0)	16 (42.1)	0.207

Statistically significant, $p < 0.05$.
MT, massive transfusion; MTP, massive transfusion protocol; nMTP, no massive transfusion protocol.

Table 2. Mean Units and Ratios of Products Transfused in General Medical/Surgical Patients

	MTP	nMTP	p Value
PRBC	12.6 ± 11.5	12.2 ± 9.0	0.864
FFP	9.2 ± 8.0	8.9 ± 8.7	0.631
PLT	7.2 ± 6.7	6.5 ± 8.6	0.183
FFP:PRBC*	0.79:1 ± 0.34:1	0.65 ± 0.39:1	0.282
PLT:PRBC*	0.61:1 ± 0.42:1	0.53:1 ± 0.54:1	0.476

All values are expressed as mean ± SD units. Statistically significant, $p < 0.05$.
*Ratios are representative of massively transfused patients.
FFP, fresh frozen plasma; MTP, massive transfusion protocol; nMTP, no massive transfusion protocol; PLT, platelets; PRBC, packed red blood cells.

period, of which, the complete transfusion and relevant clinical data were available for 52 patients. Of these 52 activations, there was an equal number of trauma and GMS patients (n = 26).

Demographics of general surgical/medical patients

The GMS indications for MTP activation included gastrointestinal bleeding (n = 12 [46.2%]), medical bleeding for other reasons (n = 4 [15.4%]), postsurgical/procedural complications (n = 9 [34.6%]), and ruptured abdominal aortic aneurysm (n = 1 [3.8%]). Indications for transfusion of GMS patients without protocol activation (nMTP) included gastrointestinal bleeding (n = 9 [23.7%]), medical bleeding for other reasons (n = 2 [5.3%]), postsurgical/procedural complications (n = 9 [23.7%]), vascular emergencies (n = 17 [44.7%]), and cerebral hemorrhage (n = 1 [2.6%]). Of the 17 vascular emergencies in the GMS nMTP cohort, 14 involved abdominal aortic aneurysms, 2 involved hemorrhages from neck vessels, and 1 was an elective aortic root repair.

Comparing patients for whom the MTP was and was not activated for nontraumatic massive hemorrhage, there was a statistically significant difference in the number of vascular emergencies ($p < 0.001$). There were no statistically significant differences in age or sex (Table 1). The nMTP patients were more likely than MTP patients to require operative intervention within 24 hours of the emergency release of PRBC units. Regardless of whether the MTP was activated, there were no statistically significant differences in 24-hour or 30-day mortality in GMS patients. There was a trend toward increased 24-hour mortality in the GMS MTP cohort; however, this data point was not adjusted for confounding factors, such as important comorbidities.

Massive transfusion protocol activation in general medical/surgical patients

Of the GMS patients for whom the protocol was activated, only 46.2% (12 of 26) were ultimately massively transfused. This indicates that there was an overactivation of the protocol in 53.8% of these patients. The high overactivation rate in this cohort is unlikely to be attributed to the death of patients before receiving ≥10 U PRBC, as only 4 of the non−massively transfused MTP patients in this study died within 24 hours of the emergency release of 10 U PRBCs. When patients who died were excluded, the overactivation rate remained elevated at 45.5%.

Component resuscitation in general medical/surgical patients

The GMS MTP patients received a ratio of FFP:PRBC of 0.79:1 ± 0.34:1 and a ratio of PLT:PRBC of 0.61:1 ± 0.42:1. Although it is still unclear what the appropriate product ratios are in GMS patients, these ratios approximated the protocol goal of 1:1:0.5 (PRBC:FFP:PLT), which was developed based on literature in trauma patients (Table 2). Activation of the MTP in GMS patients resulted in a trend toward increased FFP:PRBC and PLT:PRBC ratios in MTP patients compared with nMTP patients, but there were no statistically significant differences. There were also no statistically significant differences in the number of PRBC, FFP, or PLT units transfused in MTP and nMTP patients (Table 2).

Product waste and time to product return in general medical/surgical patients

To determine whether there were any disadvantages to the use of an MTP in terms of resource allocation, the number of units wasted (Table 3) and the time to return unused units were analyzed. In GMS MTP patients, there was a statistically significant increase in the percentage of wasted platelet units compared with GMS nMTP patients (MTP 12.8% vs nMTP 8.1%; $p = 0.046$). There were no statistically significant differences in either wasted PRBC or FFP units between these same 2 groups. The time to return PRBC, FFP, and PLT units to the blood bank did not differ significantly between MTP and nMTP groups (data not shown).

Table 3. Units Wasted When Products Were Issued for General Medical/Surgical Patients

	MTP		nMTP		
	n	%	n	%	p Value
PRBC	3/613	0.49	3/848	0.35	0.700
FFP	1/406	0.25	4/553	0.72	0.403
PLT	39/304	12.8	29/358	8.1	0.046*

Values are expressed as percentage of units wasted out of total units issued.
*Statistically significant, $p < 0.05$.
FFP, fresh frozen plasma; MTP, massive transfusion protocol; nMTP, no massive transfusion protocol; PLT, platelets; PRBC, packed red blood cells.

Time to release of fresh frozen plasma and platelets in general medical/surgical patients

Activation of the MTP significantly accelerated the delivery of component products for GMS patients (Table 4). The FFP units were issued a median of 7 minutes earlier in MTP patients than in nMTP patients (MTP: median 1.0 minute; interquartile range [IQR] 0.0 to 2.0 minutes vs nMTP median 8.0 minutes; IQR 0.0 to 37.5 minutes; $p = 0.009$), and PLT units were issued 17 minutes earlier (MTP: 7.0; IQR 0.0 to 15.0 minutes vs nMTP 24.0 minutes; IQR 9.0 to 96.0 minutes; $p = 0.010$). In the nMTP patients, there was a larger distribution and a higher degree of variability in the time to issue of both FFP and PLT units when compared with MTP patients, as evidenced by the larger interquartile ranges. This indicates a consistent practice of rapid release when the protocol was used. In fact, 14 nMTP patients had delays exceeding 15 minutes until FFP issue (3 were never issued FFP), and 17 nMTP patients had delays exceeding 15 minutes until PLT issue (9 were never issued PLT). All patients who received an MTP had an FFP issue time of <10 minutes, and all but 5 MTP patients had a PLT issue time of <15 minutes.

Implications of protocol use in trauma patients

To understand whether there were any unique challenges to MTP activation in GMS patients, we next analyzed the same outcomes from trauma patients during the same time period. Because attempting to compare outcomes such as mortality between trauma and GMS patients would require a comparison of clinically different populations, this analysis focused on measures of resource allocation. Of the 26 trauma patients for whom the protocol was activated (MTP), 21 were massively transfused (80.8%) (Table 5). This indicates that there was an overactivation rate of 19.2%, which was significantly lower than that of the GMS cohort. Of the 74 trauma patients who did not receive protocol activation (nMTP), only 14 (18.9%) required massive transfusion.

Both MTP and nMTP trauma patients received product ratios that approximated the protocol goal (Table 5). Similar to GMS patients, there was an increase in wasted platelet units in trauma MTP patients compared with trauma nMTP patients (MTP 12.2% vs nMTP 4.0%; $p < 0.001$) (Table 5). Importantly, during 23.1% of all MTP activations (trauma and GMS), at least 1 platelet unit was wasted. The MTP activation in trauma patients was also associated with a small, but statistically significant increase in FFP unit waste (MTP 1.36% vs nMTP 0.11%; $p = 0.002$) (Table 5), which was not observed in the GMS cohort.

The time to return PRBC, FFP, and PLT units to the blood bank did not differ significantly between trauma MTP and nMTP groups (data not shown); however, the delivery of component products was significantly accelerated in a similar fashion to that observed in GMS patients. Fresh frozen plasma units were issued a median of 3.0 minutes earlier (MTP: median 0.0 minute; IQR 0.0 to 3.0 minutes vs nMTP: median 3.0 minutes; IQR 0.0 to 39.0 minutes; $p = 0.007$) and PLT units were issued 3.5 minutes earlier (MTP: 5.5 minutes; IQR 0.0 to 10.3 minutes vs nMTP 9.0 minutes IQR 3.0 to 82.0 minutes; $p = 0.042$) to trauma patients (Table 5). Similar to the GMS group, the use of MTP in trauma patients resulted in a more consistent early release of blood components, as 24 nMTP patients had delays exceeding 15 minutes until FFP issue (9 were never issued FFP), and 17 nMTP patients had delays exceeding 15 minutes until PLT issue (37 were never issued PLT). All but 1 patient who received an MTP had an FFP issue time of <10 minutes, and all but 3 MTP patients had a PLT issue time of <15 minutes.

Table 4. Median Time to Issue Fresh Frozen Plasma or Platelets Relative to Packed Red Blood Cells in General Medical/Surgical Patients

	MTP	nMTP	p Value
FFP	1.0 (0.0–2.0)	8.0 (0.0–37.5)	0.009*
PLT	7.0 (0.0–15.0)	24.0 (9.0–96.0)	0.010*

All values are expressed as median (interquartile range) time (minutes).
*Statistically significant. $p < 0.05$.
FFP, fresh frozen plasma; MTP, massive transfusion protocol; nMTP, no massive transfusion protocol; PLT, platelets.

DISCUSSION

Several recent studies have demonstrated reduced morbidity and mortality in trauma patients massively transfused in accordance with an MTP.[7,9-13] The vast majority of the studies on MTP use, however, have studied trauma patients exclusively. In fact, the current widely accepted triggers for activating an MTP are all based on trauma literature. In one of the only studies

Table 5. Protocol Use in Trauma Patients and its Implications on Resource Allocation

Variable	MTP	nMTP	p Value
Age, y, mean ± SD	38.3 ± 19.5	37.8 ± 18.7	0.812
Male, n (%)	23 (88.5)	66 (89.2)	1.000
Received MT, n (%)	21 (80.8)	14 (18.9)	<0.001*
FFP:PRBC,† mean ± SD	0.85:1 ± 0.27:1	0.73:1 ± 0.25:1	0.173
PLT:PRBC,† mean ± SD	0.43:1 ± 0.35:1	0.49:1 ± 0.41:1	0.685
PRBC wasted, n (% of total issued)	6/922 (0.65)	4/1,564 (0.26)	0.188
FFP wasted, n (% of total issued)	9/660 (1.36)	1/942 (0.11)	0.002*
PLT wasted, n (% of total issued)	40/329 (12.2)	13/323 (4.0)	<0.001*
Time to issue FFP, min, median (IQR)	0.0 (0.0−3.0)	3.0 (0.0−39.0)	0.007*
Time to issue PLT, min, median (IQR)	5.5 (0.0−10.3)	9.0 (3.0−82.0)	0.042*

*Statistically significant, $p < 0.05$.
†Ratios are representative of massively transfused patients.
FFP, fresh frozen plasma; IQR, interquartile range; MTP, massive transfusion protocol; nMTP, no massive transfusion protocol; PLT, platelets; PRBC, packed red blood cells.

analyzing the use of an MTP in GMS patients, Morse and colleagues[17] found that the MTP was just as effective to deliver protocol-specified product ratios in this patient population as it was in trauma patients. They also noted, however, that in GMS patients, the MTP was more frequently overactivated, which they defined as the percentage of patients for whom the protocol was activated, but who were never massively transfused. The authors expressed concern that this overactivation rate resulted in inefficient product use. This current study was designed to investigate whether an MTP could be used effectively in GMS patients without significantly impacting resource allocation.

In concordance with the results of Morse and colleagues,[17] we found at our institution that GMS patients were transfused with similar ratios as trauma patients and that these ratios approximated our protocol goal. At the time of this study, our protocol specified a ratio of 1:1:0.5 for the initial release of products. There were no statistically significant differences between MTP and nMTP cohorts, suggesting that clinicians at our institution can practice hemostatic resuscitation even when the protocol is not formally activated. There was, however, a trend toward higher FFP:PRBC and PLT:PRBC ratios in GMS MTP patients compared with GMS nMTP patients.

Results of this analysis also suggest that in GMS patients compared with trauma patients, the MTP was more frequently activated in patients who ultimately did not go on to receive massive transfusion (defined by Morse and colleagues[17] as "overactivation"). The rate of overactivation in GMS patients was much higher (53.8%) than that for trauma patients (19.2%). Although there are several validated algorithms to predict massive transfusion in trauma patients,[18-20] these have yet to be developed for application globally in the nontrauma setting, which might contribute to the differences seen in this study between the GMS and trauma overactivation rates.

Despite the concordance with previous authors that an MTP was activated more commonly in GMS patients who subsequently did not receive massive transfusion, it is unclear whether this overactivation actually presents a challenge to resource allocation or an inefficiency, as proposed by others.[17] To investigate the impact of MTP activation in GMS patients on resource allocation, we analyzed the number of units wasted, time to return an unused unit, and time to issue FFP and PLT units after the release of 10 U PRBCs. Although no significant difference in the time to return unused units was observed, MTP activation was associated with a significant increase in PLT waste. Importantly, however, this was true in both trauma and GMS patients. An overall surprising finding in the analysis was that PLT units were wasted in 23.1% of all MTP activations, which is a similar finding to analyses reported previously.[21] In our institution, the issue of platelet waste does not appear to be unique to GMS patients, but rather is a substantial global concern supporting a need for routine follow-up of components after a protocol has been activated. We additionally demonstrated that trauma patients (but not GMS patients) had a higher likelihood of FFP waste after MTP. Others have demonstrated that achieving substantial reductions in waste is possible with tight protocol compliance and attention to product management, which should be globally advocated to all institutions that use an MTP and are now in place at our institution.[21]

Our study additionally highlights the ability of an MTP to facilitate earlier issue of products. This is likely due to a combination of earlier recognition of the need for component product, improved communication between the blood bank and the requesting physician,

and the presence of an overall more efficient process. The importance of early product delivery and transfusion in improving outcomes in massively transfused patients has been emphasized in several studies.[1,5,6,13] Although earlier product issue was found in both GMS and trauma patients, the difference between the MTP and nMTP groups was more prominent in GMS patients. General medical/surgical patients who were massively transfused without protocol activations were subject to more frequent delays in the request for and/or issue of blood components. It is worth noting that in both groups there was significantly greater variability in the time to issue of products in the nMTP cohorts, suggesting that MTP activation facilitates a more organized and consistent process of product request and issue.

At the time of this study, it was not a violation of our protocol to request $\geq$10 U PRBC without activating the MTP. As a result of this analysis, our institutional protocol has been revised to ensure that patients requiring large PRBC releases receive MTP activation. Our trauma protocol now includes indications for protocol activation based on the Assessment of Blood Consumption massive transfusion predictors.[19] There is still, however, a lack of evidence supporting specific predictors in GMS patients, and this remains an exciting area of future investigation.

Another finding of this study was a discrepancy between different services in our hospital with respect to protocol activation for massively bleeding GMS patients. Of the 18 vascular emergencies, only 1 resulted in MTP activation. All vascular emergencies were managed in the operating room by surgeons and anesthesiologists who are familiar with massive transfusion and hemostatic resuscitation. Patients with gastrointestinal bleeds, however, were managed predominantly by medical services and were more likely to receive MTP activation (12 of 21 [57.1%]). Although patients managed with or without protocol activation still received hemostatic resuscitation in accordance with our protocol, MTP activation was associated with faster and more consistent product release. These data reflect an important quality control measure and have and will continue to be used for education of our anesthesia, critical care, and surgical services.

There are several limitations of this study. The retrospective design does not control for all potential confounders and therefore we can only report associations and not causation. It is also important to note that this was a single-center analysis, and the results might not be applicable to institutions who use different MTPs. Finally, based on the design of our study and the difficulty in comparing the highly different clinical course of trauma and GMS patients, we cannot comment on what implications these findings had on patient outcomes. Although there was a trend toward increased 24-hour mortality in the GMS MTP cohort, this data point was not adjusted for confounding factors, such as important comorbidities. Rather, the intent of this analysis was to focus on resource allocation and efficiency of product delivery using the MTP.

CONCLUSIONS

In our single-center analysis, both trauma and GMS MTP patients were transfused with product ratios approximating our protocol goal. Despite finding that our MTP is overactivated in GMS patients, we could identify no unique disadvantages to its use in this population with respect to resource allocation. In fact, a potential advantage to MTP activation exists in that products are issued faster with less variability in time to distribution. Our findings of increased platelet waste were not unique to GMS patients and support the need for routine follow-up after MTP activation in both trauma and GMS patients to ensure that products are returned appropriately. Additional studies are needed to identify reliable predictors of the need for MTP activation in GMS patients and to evaluate the outcomes of MTP use in this group; however, these data suggest that an institutional MTP designed for trauma can be used for the efficient delivery of blood and blood components to the massively hemorrhaging GMS patient.

Author Contributions

Study conception and design: McDaniel, Neal, Sperry, Alarcon, Raval

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