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Minimizing Time to Plasma Administration and Fresh Frozen Plasma Waste: A Multimodal Approach to Improve Massive Transfusion at a Level 1 Trauma Center

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ABSTRACT

Massive transfusion protocols are part of damage control resuscitation for hemorrhaging trauma patients with the goal of returning the patient to hemodynamic stability. It is essential that patients receive blood products immediately and in the proper ratios. At our metropolitan Level 1 trauma center, we identified several challenges to deploying massive transfusion rapidly and within the recommended ratio guidelines. In 2016, we implemented a quality improvement project addressing 4 opportunities: fresh frozen plasma (FFP) bag breakage, plasma options, blood bank equipment, and multidisciplinary policy revision. Implementing packaging and shipping improvements, utilization of new products, and updating protocols have resulted in a 50% decrease in FFP bag breakage rates, a dramatic decrease in time for patients receiving massive transfusion to receive plasma products (mean time 3.5 min), and patients being administered the recommended ratio of blood products.

Key Words

Hemorrhage, Liquid plasma, Massive transfusion protocol (MTP), Trauma

Preventable death after injury is defined as those casualties whose lives could have been saved by appropriate and timely medical care, irrespective of tactical, logistical, or environmental issues (Berwick, Downey, & Cornett, 2016). When evaluating deaths from traumatic injury, hemorrhagic shock continues to be the leading cause of preventable death (Spinella, 2017). Damage control resuscitation (DCR) strategies were developed to address uncontrolled hemorrhage. These strategies include minimizing crystalloid infusion, permissive hypotension, and balanced resuscitation with early plasma, platelets, and red blood cells (RBCs) (Holcomb et al., 2015).

The American College of Surgeons (ACS) and the Eastern Association for the Surgery of Trauma (EAST) have established best practice guidelines to direct DCR and MTP for trauma patients experiencing uncontrolled hemorrhage. These guidelines include early and rapid deployment of blood products in a ratio of 1:1:1, plasma to RBCs to platelets (ACS, 2013; Cannon et al., 2017). Trauma centers should review the ACS guidelines and compare their current practice with the guidelines, identifying areas that need modifications to align with current recommendations.

Massive transfusion is a high-risk, low-frequency event for most hospitals. Our facility admits more than 2,600 trauma patients per year. On average, 25 patients per year receive MTP. Consistent monitoring of MTP in comparison with MTP guidelines can identify opportunities for improvement.

METHODS

One recommendation from the ACS Trauma Quality Improvement Program (TQIP) massive transfusion guideline states that universally compatible RBCs and thawed plasma should be immediately available (ACS, 2013). Our facility had identified an opportunity for improvement with the frequency of bag breakage (and waste) when thawing fresh frozen plasma (FFP). Our facility was experiencing bag breakage rates between 10.7% and 14.5%. All bags of FFP are visually inspected before being thawed, but there can be tiny holes or tears in the bags that are not visible. The holes occur during the manufacturing, shipping, and processing of the FFP bags before thawing in the facility's blood bank. These holes are only identified after thawing. Two common methods for thawing FFP are the use of a water bath thawer and a microwave. Water bath thawers and microwaves typically take 20 and 10 min, respectively, to thaw a bag of FFP. After identifying a bag with a hole in it, the bag of FFP is unusable and the process of thawing would begin again, creating significant delays in

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The authors declare no conflict of interest.

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DOI: 10.1097/JTN.0000000000000460

delivering plasma to hemorrhaging patients. After identifying a high rate of bag breakage, the blood bank coordinator contacted two major national blood product suppliers, Bonfils Blood Center (now Vitalant after acquisition and name change) and American Red Cross, to assess and track broken FFP bag rates related to the manufacturing, packing, and shipping processes. Both organizations agreed to investigate the issue further. Bonfils Blood Center identified a trend in the broken FFP bag rates with one specific bag type used to hold the FFP. It agreed to discontinue using the bag with the high failure rate. The American Red Cross identified an increased rate of broken plasma bags when using a specific shipping company. It formed a nationwide working group to evaluate the shipping process for blood products. Through the working group, it identified an issue with the packaging materials used by the shipping company. The American Red Cross then changed the packaging materials used to ship its product in an attempt to decrease defective products.

Plasma is essential for controlling hemorrhage during massive transfusion because it contains proteins for blood clotting. In the United States, there are seven plasma products available, four frozen plasma products and three liquid state products (American Association of Blood Banks, 2017). Two of the liquid state products are derived from FFP in the form of thawed plasma. The third liquid product is liquid plasma. Liquid plasma is unique in that it is never frozen. It is separated from whole blood and stored at 1–6 °C. Liquid plasma provides several benefits during massive transfusion. The immediate availability of the product eliminates delays in plasma support during MTP. Snyder et al. (2009) found in their study regarding the delivery of blood products during MTP the medium time to the first unit of RBCs was 18 min whereas the medium time to the first unit of plasma was 93 min. With the use of liquid plasma, blood products can then be issued in correct ratios instead of trying to "catch up" with plasma products during the MTP. When utilizing liquid plasma in the initial phases of MTP, it provides sufficient time to thaw additional FFP for continued massive transfusion. There is potential for less waste when using liquid plasma than with thawed plasma due to the longer shelf life. Liquid plasma has a refrigerated shelf life of 26 days versus 5 days for thawed plasma (American Association of Blood Banks, 2017). One consideration to the implementation of liquid plasma is the coagulation profile. Plasma contains all coagulation factors necessary for clotting. These coagulation factors are responsible for the formation of a blood clot when activated as part of the coagulation cascade. In evaluating the effectiveness of liquid plasma, Gosselin et al. (2013) found that there was a decrease in Factor V, Factor VII, Factor VIII, and von Willebrand factor on Day 15 of storage of liquid plasma. Factor V and von Willebrand factor decreased approximately 30% across all samples. Factor VII and Factor VIII also decreased significantly ranging from 5% to 22% between all samples. Factor II, Factor X, and Factor XIII showed minimal changes during storage. Although there is a demonstrated decrease in coagulation factors of liquid plasma over time, it maintains at least 50% of factor activity and thrombin-generating capacity (Backholer et al., 2017). Additional research has compared liquid plasma with thawed plasma to compare two immediately available products. Backholer et al. (2017) found liquid plasma to be comparable with thawed plasma in hemostatic variables. Matijevic et al. (2012) found the hemostatic profile of liquid plasma to be better and sustained five times longer than thawed plasma. Their research demonstrated that in liquid plasma, most coagulation factors were stable at 26 days of storage and retained at least 88% of the initial activities, which was better in comparison with thawed plasma stored at 5 days. They also found liquid plasma to have a significant number of residual platelets, which contribute to clot strength. The platelets are destroyed in the freeze–thaw cycle of thawed plasma. In summary, liquid plasma provides superior shelf life than thawed plasma or FFP (Van, Holcomb, & Schreiber, 2017). There are some limitations to utilizing liquid plasma. Currently, the only indication for liquid plasma is the initial treatment of patients receiving massive transfusion (American Association of Blood Banks, 2017). Liquid plasma has a shelf life of 26 days, which is longer than thawed plasma with a shelf life of 5 days, but significantly shorter than that of FFP with a shelf life of 365 days when it remains frozen. Liquid plasma has been used in Europe since the 1980s but only recently has become utilized regularly in the United States (Backholer et al., 2017; Gosselin et al., 2013). Although liquid plasma usage has become more frequent, it is still not widely used across the country. After reviewing the research and evaluating the risks and benefits of liquid plasma in our protocol, our multidisciplinary process improvement team chose to implement the use of liquid plasma for the initial phases of massive transfusion.

Hospitals can choose to use microwaves or water baths in their blood banks to thaw plasma. The blood bank may take into consideration speed of thawing, expense of machines, how many blood products are utilized, and the types of blood products utilized at the facility. Microwave thawers are more expensive but can thaw products quickly. They are also limited in that they are not approved to thaw cryoprecipitate, another blood product used as an adjunct during MTP. Water bath thawers are less expensive and thaw products evenly but can take more time to thaw products. At this Level 1 trauma center, we have two microwaves that can each thaw 1 unit of plasma at a time and two water bath thawers that can each thaw 2 units of plasma. As our water bath thawers were coming to the end of their "useful life," the blood bank investigated upgrading

our thawers to decrease the amount of time for the thawing process. The old water bath thawers took approximately 20 min to thaw a bag of plasma. Our new upgraded units can thaw a bag of FFP in 12 min. Massive transfusion requires a large amount of products, and this new equipment has made the FFP available in a timelier manner.

Policies, guidelines, and practice should always reflect current research-based evidence. Recent studies show that patients receiving transfusion of plasma, platelets, and RBCs in a 1:1:1 ratio during massive transfusion achieve hemostasis and fewer experienced death at 24 hr due to exsanguination (Holcomb et al., 2015). As we reviewed our current policy, we found that our policy did not reflect best practices in providing patients with a 1:1:1 ratio of blood products during massive transfusion. Furthermore, upon review of several past MTP patients, we were not meeting the best practice standard for the product ratio set by the ACS to transfuse plasma and RBCs in a ratio between 1:1 and 1:2 (ACS, 2013). The majority of MTP patients were receiving high quantities of RBCs before receiving any plasma products, making it difficult to achieve the recommended ratios. Policy revision for hospital-wide policies requires participation from all units the policy affects. A multidisciplinary team including the trauma nurse coordinator, trauma medical director, chief medical officer, emergency department physician director, critical care physician director, anesthesia liaison, blood bank coordinator, and pathologist met to make revisions to the policy. After reviewing ACS TQIP guidelines, current research, and comparing our policy, the policy was revised. The revisions included adding the use of liquid plasma and adjusting the ratio of blood products. The revised policy uses a 1:1:1 ratio for plasma, platelets, and RBCs. The updated policy went through the approval of several hospital committees and was then implemented by all departments.

This project was reviewed by the institutional review board and hospital administration and designated as a quality improvement project.

RESULTS

The blood bank monitors bag breakage rates for FFP. Before working with the blood product suppliers on improving the production and shipping process, the mean rate of broken FFP bag was 12.6%. After both of the blood suppliers made changes to their process, the rate decreased. In 2017, the facility thawed 1,213 units of FFP. Seventy-six of those units were broken upon thawing for a rate of 6.3%. In 2018, the facility thawed 1,087 units of FFP. Fifty-four of those units of FFP were broken upon thawing for a rate of 5.0%. There is some variability in FFP bag breakage rates on a month-to-month basis, as the overall usage of FFP for the facility fluctuates. There has been a consistent decrease in bag breakage as we continue to monitor rates (Figure 1).

To monitor for improvement after the implementation of liquid plasma, we evaluated time from initiation of massive transfusion to the first unit of plasma through retrospective chart review. Twenty-four patient charts were reviewed, eight before implementing liquid plasma and 16 postimplementation. Before having liquid plasma available at our facility, the median time from MTP initiation to plasma was 31.5 min (range, 15–64 min). After implementing liquid plasma, the median time was 3.5 min (range, 0–10 min) (Figure 2). Updating FFP thawing equipment in the blood bank has decreased the amount of time to thaw FFP from 20 to 12 min. The new equipment makes FFP available faster.

Following multidisciplinary revision of the MTP policy, there has been a significant improvement in ratios of blood products for patients receiving massive transfusion. All trauma patients receiving massive transfusion have since met the ACS guidelines for massive transfusion.

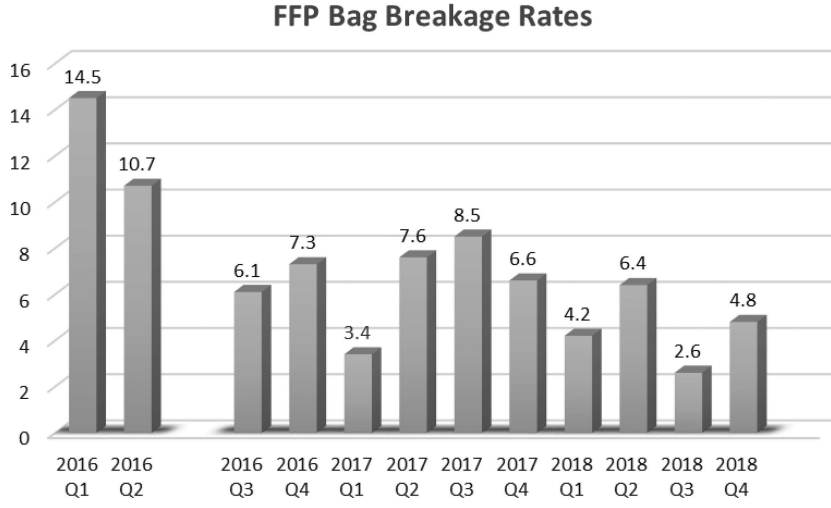

Figure 1. FFP bag breakage rate by quarter. FFP = fresh frozen plasma.

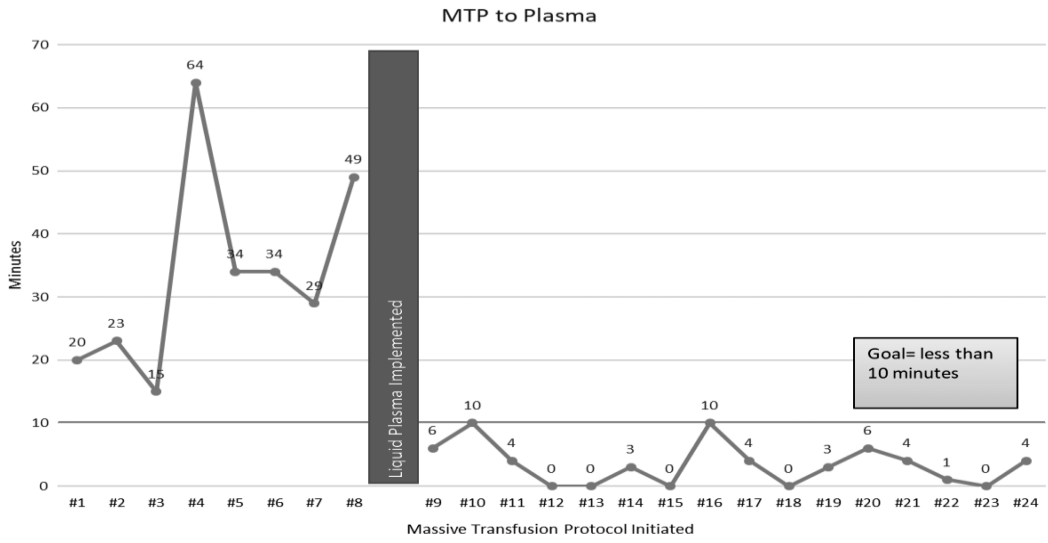

Figure 2. Time from MTP initiation to plasma. MTP = massive transfusion protocol.

DISCUSSION

Employing four separate interventions to improve massive transfusion at our facility has had positive results. First and most impactful, both of our blood suppliers have implemented change in their processes, resulting in a reduction in the frequency of FFP bag breakage. Our facility's FFP bag breakage rates decreased from 12.6% to 6.3%. This process improvement should have a similar impact on other facilities across the nation that utilize the same suppliers.

Second, we implemented the use of liquid plasma as part of massive transfusion. Liquid plasma has had a huge impact on the timeliness for hemorrhaging patients to receive plasma products. The goal was for all patients receiving massive transfusion to have their first unit of plasma administered in less than 10 min. There has been a dramatic and consistent decrease in the amount of time for patients to receive plasma products. While understanding there are limitations to using liquid plasma, we are able to deploy plasma early and in a correct ratio to other blood products.

Third, the blood bank identified equipment that had come to the end of its useful life. This provided our facility an opportunity to obtain the most current equipment and technology for FFP thawing. This was an additional opportunity to improve the availability of plasma products for massive transfusion.

Finally, the facility implemented a revised policy that reflected best practice guidelines set by the ACS. Policy change is a lengthy and involved process, especially when it affects several departments within a hospital. The first step was to identify deficiencies in the current policy in comparison with best practice guidelines and current research. Then, department leadership met to revise the policy. The group included the hospital chief medical officer, trauma medical director, trauma program manager and staff, emergency department medical director, critical care director, anesthesia physician liaison, lab director, and blood bank coordinator. It was essential that all departments involved with MTP were in agreement with the policy updates. The group agreed upon modifications to the policy, making it compliant with the ACS best practice guidelines. The policy updates then had to be approved through several hospital committees, including the trauma process improvement and patient safety (PIPS) committee, before formal changes were approved and published for hospital practice. Providing recent research and current standard recommendations assists in implementing change in a policy. Our policy now reflects best practice with proven improvements in morbidity and mortality. Concurrent, continuous monitoring will ensure that practice complies with these changes.

LIMITATIONS

This process improvement project was conducted at one facility that does not have a high volume of patients receiving massive transfusion. A larger number of facilities tracking and reporting FFP bag breakage from the same blood supplies would strengthen the conclusions. Additional facilities monitoring the time from MTP initiation to plasma while utilizing liquid plasma would also support the conclusions made. Currently, at our facility, liquid plasma is stored and maintained in the blood bank due to the infrequent use and relatively short expiration. Ideally, liquid plasma would be available in the emergency department in conjunction with the O− blood. With both RBCs and plasma immediately available in the trauma bay, MTP can be initiated with ratios in compliance with ACS best practice guidelines. Plasma is the least expensive

product used during MTP, although cost is a still a consideration. Currently, liquid plasma costs approximately $5 more per bag than FFP and liquid plasma has a limited shelf life (26 days) compared with FFP. Liquid plasma is not approved for other uses within the facility and must be disposed of at its expiration. This can potentially lead to an increased expense to have plasma readily available at all times. Although we have seen significant improvements within our facility, we have a relatively low volume of patients who receive massive transfusion. Our facility has now implemented thromboelastography, which will modify the MTP process from a ratio-based transfusion to a goal-directed therapy. Results are not yet available.

CONCLUSION

Meeting the guidelines set forth by the ACS and EAST for massive transfusion can be challenging for any trauma center. Clearly identifying the issues and then working collaboratively within and outside the hospital can lead to positive changes impacting patient care. Having plasma immediately available during massive transfusion can be difficult due to issues with timing and the thawing process. Liquid plasma can be considered by facilities to improve the availability of plasma and the time to administration of plasma. The use of liquid plasma has had a positive impact on patients receiving the appropriate blood products in a timely manner and in the ratios consistent with the guidelines set forth by the ACS and EAST.

KEY POINTS

- Implementing liquid plasma in MTP proved to significantly decrease the amount of time for hemorrhaging patients to receive plasma.
- Collaborating with national blood suppliers on reducing the rate of FFP bag breakage has created a greater reliability in the availability of product during massive transfusion.
- Early delivery of plasma to patients receiving massive transfusion has facilitated trauma patients receiving blood products in ratios in compliance with the ACS recommendations of 1:1:1.

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DOI: 10.1097/JTN.0000000000000464