Joint AABB-THOR Working Party Petition

The following individuals endorse the following statement:

"Do you agree that AABB standards should allow for uncrossmatched, low titer, group O WB to be used in the resuscitation of massively bleeding patients whose ABO group might not be known at the time of WB transfusion?"

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Proposal to modify Standard 5.15.1 to permit the use of low titer, group O whole blood in massively bleeding patients regardless of their ABO group

Proposal

The AABB/THOR working party (WP) is recommending that the AABB Standards Committee modify standard 5.15.1 to permit the use of low titer, group O whole blood (WB) in all massively bleeding patients regardless of their ABO group. The WP recommends deleting the requirement for administering WB in an ABO-identical manner from 5.15.1, and creating a new standard and substandard as follows:

New standard 1: Low titer, group O whole blood can be administered in an uncrossmatched manner to recipients with a life-threatening hemorrhage regardless of the recipient's ABO group.

New standard 1.1: Low titer WB shall be defined as <200 for both anti-A and –B.

Background

There is extensive literature and experience indicating that it is desirable and safe to use cold stored, low antibody titer WB early in the management of traumatic hemorrhagic shock.[1] Reports from the Korean war detailed the efficacy and safety of transfusing low titer Group O whole blood; in 1952 over 600,000 units of low titer (defined as <256) group O whole blood were transfused to combat casualties. Patients typically received 10-30 units of low titer, group O WB, and only 4 patients were noted to have post-transfusion hemoglobinuria, which might or might not have been related to the receipt of the WB.[1] During an approximately 18 month period during the Vietnam war, 230,323 WB units were transfused,[2] and only one hemolytic reaction to a group O unit was reported. In fact, this lone, non-fatal reaction

only occurred because a labeled high titer group O unit was accidentally transfused to a group A recipient.[3]

The recent wars in Iraq and Afghanistan have highlighted the high mortality associated with traumatic hemorrhagic shock and provided the opportunity to reevaluate the potential benefits of WB resuscitation in this context. One analysis from Iraq indicated the use of WB was independently associated with improved 30 day survival compared to the use of blood components for US casualties with life-threatening hemorrhage.[4]

Reducing death from hemorrhage is essential since the mortality for patients with traumatic hemorrhagic shock is high (approximately 20%) and there are approximately 30,000 preventable civilian deaths due to traumatic hemorrhage per year in the US alone.[5] The rationale for the use of group O WB early in the resuscitation of massively bleeding patients is multifactorial and has been recently reviewed.[5,6] Group O whole blood provides a balanced resuscitation that simultaneously addresses oxygen debt and coagulopathy, both of which are associated with high mortality in this population.[4,7,8] The use of a blood based transfusion strategy that approximates whole blood with 1:1:1 unit ratios has been shown to reduce death from hemorrhage in adult trauma patients.[4,8] Whole blood is a more concentrated product containing a smaller quantity of anticoagulant and preservative solutions compared to an equivalent amount of reconstituted WB from blood components.[4] The cold stored platelets in WB improve hemostasis more effectively compared to platelet units stored at room temperature (RT). [9,10] Improved hemostasis with platelets stored at 4C has been extensively reviewed and is based on a significant amount of in vitro data and 2 RCTs.[9-12] One RCT in children demonstrated reduced blood loss and improved platelet aggregation in the cold stored whole blood arm compared to those in the conventional components arm who were transfused with RT stored platelets in a 1:1:1 ratio.[13] Another trial of adults on aspirin showed improved correction in the bleeding time when a cold

stored platelet unit was transfused compared to a conventional RT unit.[14] Furthermore, the use of WB will greatly simplify the logistics of the resuscitation by transfusing the contents of one bag instead of up to three bags that all have to be separately procured and transported from the blood bank under different temperature conditions. This latter advantage is especially important in the pre-hospital setting where space in the helicopter or ambulance is at a premium, and often intravenous (IV) access in the patient is limited. The ability to quickly provide a transfusion to traumatically injured patients has been shown to improve outcomes in both military and civilian trials,[15,16] and it is known that mortality is increased by 5% for every minute that initiating a transfusion was delayed in these patients.[16] Since it is not feasible to transport RBCs, plasma and platelet units in the prehospital setting, the most effective method of resuscitating a patient with traumatic hemorrhagic shock in the prehospital setting is with WB. Effective resuscitation in the prehospital phase of treatment is essential because of the 30,000 preventable deaths per year in the US due to traumatic hemorrhage, approximately 25,000 of these deaths occur in the prehospital phase of resuscitation.[5,17]

A major limitation to implementing low titer group O WB at civilian medical centers is the AABB standard regarding its use. The AABB's Standards for Blood Banks and Transfusion Services require that WB units be ABO-identical with the recipient (standard 5.15.1 in the 31st edition of the standards). There is a theoretical concern that a minor incompatible plasma transfusion could lead to hemolysis of the recipient's RBCs. However, a subsequent standard permits the transfusion of minor incompatible plasma so long as the transfusion service has a policy guiding this practice (standard 5.15.4 in the 31st edition of the standards). According to the latter standard, a minor incompatible transfusion of group O platelets or plasma could be administered to a group A recipient, as long as the transfusion service has a policy that permits this practice. Therefore, there is a circularity in the AABB standards: a transfusion service is permitted to transfuse the minor incompatible plasma in platelets and plasma units, but not from WB. Standard 5.15.4 does not provide guidance on the number of units or the total quantity of

minor incompatible plasma that can be transfused, any specific donor-recipient ABO pairings that are forbidden, what to do with group O minor incompatible units in particular, whether an antibody titer must be performed on the minor incompatible product before it is transfused, or under which clinical circumstances minor incompatible plasma may be transfused – all of this is left to the discretion of the individual transfusion service's medical director. It therefore remains unclear why the regulation of WB transfusion was specifically excluded from Standard 5.15.4.

The safety of transfusing minor incompatible plasma, mainly through platelet transfusions, is well documented. In 2015, there were nearly 2 million apheresis and whole blood platelet units transfused in the US,[18] and in the United Kingdom there were over 300,000 doses issued to hospitals in 2016.[19] Many of these transfusions would surely have featured a minor incompatibility between donor and recipient.[20] Yet the number of times that recipients experienced a hemolytic episode from the minor incompatible plasma in the platelet dose remains very small, on the order of a few case reports (reviewed in references 21 and 22). Furthermore, in a study of 16 hematology/oncology patients who received at least one ABO-identical and a minor mismatched platelet transfusion within a 24 hour period,[23] Mair and Benson found that there was no significant difference in the mean change in hemoglobin concentration following the ABO-identical vs. the minor mismatched platelet transfusions. This indicates that hemolysis did not occur following the transfusion of the minor mismatched platelet unit in spite of the fact that most of the minor incompatible platelets were group O; these units potentially have higher titers of anti-A and/or anti-B compared to platelets from the other blood groups and are considered to be the highest risk product in terms of causing hemolysis following a minor incompatible transfusion. None of these minor incompatible platelet transfusions were shown to contain low titers of anti-A and/or –B, and yet significant hemolysis did not occur. Furthermore, traumatically injured patients are often transfused with large quantities of platelet units. In fact, in the recent PROPPR trial the median number of whole blood platelet units transfused in the high ratio group

was 12 (effectively a double dose of platelets in adults) within the first 24 hours.[8] A double dose of platelets contains approximately 600 ml of potentially minor-incompatible plasma. Thus, it is commonplace to provide traumatically injured patients with large quantities of potentially incompatible plasma.

The safety of the use of group A plasma in trauma (STAT) study demonstrated that group B and AB trauma recipients who received an average of 4 units of group A plasma during their resuscitation did not have increased early- or in-hospital mortality, or longer hospital lengths of stay compared to group A trauma patients who also received group A plasma.[24] There were also no reported acute hemolytic reactions reported amongst these B and AB recipients. Importantly, the vast majority of the participating hospitals in this study (76%) did not titer the anti-B in the plasma and were thus not intentionally providing low titer units to their trauma patients, and yet there were no demonstrably worse outcomes amongst the B and AB recipients who received minor incompatible plasma transfusions compared to those who received fully compatible transfusions.

The safety of using cold stored, low titer (<50 anti-A and –B by manual saline tube immediate spin without enhancements) WB in traumatically injured civilian patients has been demonstrated.[25,26] In a study of 27 non-group O and 17 group O recipients, there was no laboratory or clinical evidence of hemolysis in the former group compared to the latter group of recipients, with the exception of a higher median level of total bilirubin amongst the non-group O recipients on the day of receipt of WB.[25] This higher median total bilirubin level was still within the normal range, and the difference in this parameter between the group O and non-group O recipients was no longer apparent on the following day. These observations have been extended to include additional recipients, and recipients of greater numbers of WB units (3 and 4 units), and there continues to be no biochemical or clinical evidence of hemolysis amongst the non-group O recipients (M. Yazer, unpublished observations). Furthermore, low titer (<50,

as described above) cold stored group O WB has also been successfully implemented at the Children's Hospital of Pittsburgh. Traumatically injured children older than 3 years and weighing more than 15 kg can receive up to 30 ml/kg of uncrossmatched group O WB. The non-O pediatric recipients did not demonstrate clinical or laboratory evidence of hemolysis compared to the group O pediatric recipients (data to be presented as an oral abstract at the 2017 AABB annual meeting).

It is interesting to note that the 5 civilian trauma centers or emergency medical systems in the US and Norway that are using group O WB have all adopted an anti-A and anti-B titer threshold of between <50 and <200 to define "low titer".[27] This could be a reasonable range for blood centers and transfusion services to consider when creating their local definition of a low titer. Thus, as the evidence from the civilian adult and pediatric experience with WB indicates, these low titer group O WB units have an enhanced safety margin compared to untitered minor incompatible plasma that is transfused with non ABO compatible platelet units. Furthermore, the fact that only low titer WB units are being issued to civilian trauma patients in the US adds yet another layer of safety and reassurance about the safety of using low titer WB in trauma patients regardless of whether their ABO group is known at the time of the transfusion or not.

The safety of transfusing minor incompatible plasma is well established and indeed this practice is permitted in the AABB standards (5.15.4) for all plasma-containing products except WB. However, the transfusion of WB to a recipient of unknown ABO group is prohibited by standard 5.15.1 thereby delaying the administration of this product to some massively bleeding patients. This prohibition is retarding the implementation of civilian pre- and early in-hospital WB transfusion programs. The AABB/THOR working party has generated a petition that has been signed by 217 experts in the fields of transfusion medicine and resuscitation medicine from 24 countries, demonstrating that there is

significant domestic and international interest in using low titer group O WB in traumatically injured patients or in others with life-threatening hemorrhage.

With the growing body of evidence indicating that low titer group O WB is serologically safe for non-O recipients in adults and children, and the increasing support and demand for this product in the US, Standard 5.15.1 should be modified to permit the use of low titer, group O WB in massively bleeding patients regardless of their ABO group. Requiring each individual medical center to submit a variance is an inefficient approach to permitting the use of low titer group O WB. Each transfusion service would also follow Standard 5.15.4 and devise a policy that specifies the definition of low titer, the quantity of group O WB that can be transfused per patient, the nature of massively bleeding patients who would qualify to receive it, and any clinical surveillance of the recipients of this product that may be necessary.

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