Low Yield Platelets: Safety and Efficacy for Patient Care

Description of Low Yield Platelets

Per current FDA regulations, calculation of the platelet yield (volume of platelet bag x platelet count concentration) must be performed on every apheresis platelet. To be labeled and distributed as a "standard-dose" apheresis platelet, the bag must contain ≥3.0 x 10^{11} platelets.[1]

Low yield (aka variable content) platelets are apheresis platelet bags that contain ***less than*** 3.0 x 10^{11} platelets; about 10-15% fewer platelets than a standard apheresis unit. Low yield platelets undergo the same collection, processing, and safety measures as all other platelet components and thus may be either pathogen-reduced (PR) or large volume delayed sampling (LVDS) platelets. After labeling with the actual platelet content, this platelet product may be distributed for patient use in the same manner as a standard apheresis platelet.

Preserving a Precious Resource: Versiti's Approach to Low Yield Platelets

A platelet donation collected via apheresis is optimized to allow for the collection to be separated or divided into 2 or 3 units, with the aim for each unit to contain 3.0 – 5.9 x 10^{11} platelets. The additional manufacturing steps required for PR and LVDS platelets[2] may result in one or more divided components having a platelet yield of less than 3.0 x 10^{11}. Rather than discard these transfusable products, those containing between 2.6 to 2.9 x 10^{11} platelets will be labeled and distributed as low yield platelets. Versiti will not distribute platelet products containing ≤2.5 x 10^{11} platelets.

Labeling Requirements & ICCBBA Product Codes

Low yield apheresis platelet product codes are different from the standard divided apheresis platelet codes and must be built into the hospital/lab IT system to allow the product to be accepted into the facility's blood inventory. The product description label for these platelets will include "Contains <3 log 11 Platelets".[3] The actual platelet yield will also be noted on the label.

Clinical Efficacy of Low Yield Platelets

The minimum requirement by the FDA[1] for a standard-dose apheresis platelet is ≥3.0 x 10^{11} platelets, which is higher than the requirements in many other countries. Internationally, the minimum platelet content for standard apheresis units ranges from 2.0 - 2.5 x 10^{11} platelets per bag. No detrimental effect or increase in platelet usage has been reported in these other countries when transfusing platelets containing a lower platelet yield.[4,5]

Clinical trials have demonstrated that low-dose *prophylactic* platelet transfusions in patients with hematologic disorders is safe. The PLADO study[6] was a randomized controlled trial comparing *prophylactic* platelet transfusion at low-dose (1.1 x 10^{11}/m^2), medium-dose (2.2 x 10^{11}/m^2), and high-dose (4.4 x 10^{11}/m^2), based on recipient body size, to *hospitalized* hematology/oncology patients. For an 80 kg male patient, this dosing strategy translated to a bag containing about 2.2 x 10^{11} platelets for low-dose, 4.4 x 10^{11} platelets for medium-dose, and 8.8 x 10^{11} platelets for high-dose. This study found no effect of platelet dose on the primary endpoint, which was the proportion of patients experiencing minor bleeding e.g. epistaxis, purpura or melena. While a low-dose platelet transfusion was as effective as a medium- or high-dose platelet transfusion, in the low-dose arm, a shorter interval between transfusions was identified to maintain the platelet count at a safe level (>10,000/μL).

A systematic review and meta-analysis of 7 randomized controlled trials[7], one being the PLADO study, compared whether different doses of *prophylactic* platelet transfusions (based on

patient body size) affect efficacy and safety in preventing bleeding in over 1800 patients with hematological disorders receiving chemotherapy and/or stem cell transplantation. The authors found that when compared to a standard or high-dose strategy, low-dose platelet transfusion was not associated with increased bleeding risk (i.e. no difference in number of participants who had significant clinical bleeding, number of days with bleeding, or time to first bleeding episode). Low-dose platelet transfusions did lead to shorter transfusion intervals and increase in the number of platelet transfusion episodes. On a side note, there was no clinical benefit of the high-dose platelet transfusion strategy over the standard-dose.

Generalizing the results of the above studies to all patients or other indications should be undertaken with caution. No studies to date have evaluated the effectiveness of different platelet dose strategies for *therapeutic* transfusions in actively bleeding patients (e.g. surgical or trauma patients). For these patients a higher platelet threshold (>50,000/mL) is desired for hemostasis. Patient factors such as weight, blood volume, clinical condition, bleeding, or impending invasive or surgical procedure should be considered when selecting platelets for transfusion. A standard-dose platelet may better meet the patient's clinical need for a higher platelet increment post-transfusion.[6]

Conclusion: Implications for Practice

Low-dose prophylactic platelet transfusions have demonstrated safety and efficacy for prevention of bleeding in thrombocytopenic hematology/oncology patients due to marrow hypoplasia. For these *hospitalized* patients, use of a low-yield platelet containing 2.6 - 2.9 x 10^{11} platelets/bag (dose generally higher than in the low-dose arm of the trials) should be considered. This practice will help optimize the utilization of an already constrained resource. For patients requiring a higher platelet count increment after transfusion or longer interval between transfusion visits, use of a standard dose platelet, when available, may be a better strategy.[7] Monitoring and assessment of the effect of the platelet transfusion is paramount for quality patient care.

References:

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