New Platelet system Destroys blood pathogens at Vanderbilt

Vanderbilt one of the first in Tennessee to get platelets treated with the Cerus Intercept system

VUMC will be one of the first in the region to benefit from a proven technology that wipes out pathogens in blood platelets. The product is expected to be in our blood bank by May-June, 2017.

The novel system, developed by Concord, Calif.-based Cerus Corp, combines a chemical based on something found in celery with ultraviolet light to chemically handcuff strands of DNA or RNA, preventing them from replicating. That stops the likes of nearly any virus, bacteria, parasite or other pathogen that relies on those long-chain nucleic acids to survive and function. The process destroys microbes such as Zika, West Nile, E coli as well as many that are not tested for in our blood supply, such as dengue, chikungunya, and <u>many others</u>, both known and otherwise. This technology virtually eliminates concerns about bacterial contamination of platelets, which continues to be a problem nationwide as a risk of platelet transfusion. Approximately 1 in 5,000-10,000 platelet units are contaminated with bacteria, depending on the estimate; for patients receiving more than one unit, the risk rises accordingly.

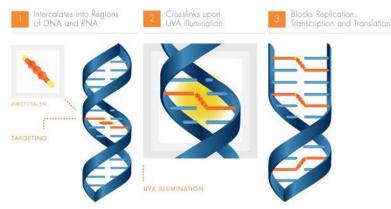
The Intercept process also stops lymphocytes and other leukocytes – a type of white blood cell – that can attack organs in stem cell transplant recipients and cause <u>graft-versus-host disease</u>. As a result, intercept platelets do not require irradiation. Leukocytes are implicated in febrile transfusion reactions as well, which should be reduced with this product.

The technology, while remarkable, is far from experimental. The U.S. Food and Drug Administration first <u>approved</u> the Cerus Intercept for platelet as well as plasma donations in December 2014 – 12 years after the Intercept earned the CE Mark in Europe.

How it works

The INTERCEPT Blood System for Platelets uses amotosalen - a well characterized photoactive compound that specifically targets DNA and RNA and UVA illumination to irreversibly cross-link nucleic acids. In doing so, INTERCEPT blocks replication of viruses, bacteria, and parasites, rendering them inactive. Amotasalen is a plant-derived compound found in citrus fruit and celery. After treatment of the unit, filtration takes out the synthetic psoralen to trace levels and the platelet unit is ready to go.

There's a premium for such platelet units — \$120 on top of the industry-standard \$550 for an untreated bag.



1) A synthetic psoralen called amotosalen

- chosen from among hundreds of candidates – docks between acid pairs. 2) Ultraviolet-A illumination activates the amotosalen, causing permanent cross-links between DNA or RNA strands. 3) Cross-linking stops replication – and with it, the pathogen or white blood cell. (Source: Cerus Corp.).

Safety

Hemovigilance (HV) programs provide a comprehensive view of transfusions and potential adverse events via the surveillance of blood donations in routine use settings. Over 300,000 INTERCEPT Blood System processed platelet units have been transfused in French and Swiss national HV programs, with no reported transfusion-transmitted infections or sepsis-related fatalities to-date.

The INTERCEPT Blood System has been evaluated in numerous clinical trials comprised of over 1000 subjects that received INTERCEPT Platelets. Primary endpoints were met in the controlled, randomized clinical trials, including corrected count increments (CCI) and bleeding criteria, both of which are measures of hemostatic efficacy. The frequency of acute transfusion reactions (ATRs) was assessed in three observational studies. Although intercept platelets were found to be overall non-inferior, the corrected count increments following transfusion (i.e. the bump in platelet count) is approximately 20% less than with a standard platelet. Hence, if your patient is requiring transfusions over a long period of time, you may find that a larger number of transfusions will be required to meet a desired platelet count.

Summary

The benefits of intercept include patient safety, particular with regard to infectious complications of platelets. Patients receiving the Intercept units seem to have fewer complications in terms of febrile transfusion reactions, in which patients spike a fever when transfused. The risk of GVHD is further reduced and the need for irradiation of platelets is eliminated.

References

Sweeney J et al. Platelet Transfusion Therapy. Bethesda: AABB Press, 2013

Agence Francaise de Securite Sanitaire des Produits de Sante, Rapport Annuel Hemovigilance 2009-2014.

Swissmedic, Haemovigilance Annual Report, 2010-2014.

Snyder E et al. Transfusion 2004;44:1732-1740.

Corash L et al. Transfusion 2000;40(S10):137.

McCullough et al. Blood 2004;104(5):1534-1541.

Janetzko et al. Transfusion 2005;45:1443-1452.

Slichter SJ et al. Transfusion 2006;46:731-740.

Schlenke P et al. Ann Hematol 2011;90(12):1457-1465.

Infanti L et al. Transfus Apher Sci 2011;45(2):175-181.

The INTERCEPT Blood System for Platelets - Dual Storage Set Package Insert, March 15, 2016