

MASAC Recommendation on Plasma Transfusion Alternatives

The following recommendation was approved by the Medical and Scientific Advisory Council (MASAC) on October 24, 1998, and adopted by the NHF Board of Directors on October 25, 1998.

Human plasma is required to correct the hemostatic defect in patients with rare hereditary coagulation deficiencies, such as factors I, II, V, VII, X, XI and XIII, for which specific therapeutic concentrates are not available. Plasma is also commonly used for blood volume expansion in patients without congenital bleeding disorders and in the treatment of other rare diseases such as thrombotic thrombocytopenia purpura (TTP). Although the risk of infectious disease transmission through fresh frozen plasma (FFP) may be considered low by historical measures, blood donations made during the “window periods” of viral infections remain problematic. There are now available two new plasma products that are capable of providing still wider margins of safety to patients requiring plasma products. These are PLAS+® SD (S/D FFP) and Donor Retested FFP (DR-FFP).

S/D FFP is commercially prepared from pools of previously frozen plasma from up to 2500 volunteer donors. The pooled material is treated with solvent, tri(N-butyl) phosphate [TNBP], and detergent, Triton-X 100, effectively inactivating lipid-enveloped viruses such as HIV and hepatitis B and C. Following steps to remove these agents, the residual plasma is recovered and distributed in 200 mL units. S/D FFP has been shown to be effective for surgical prophylaxis in patients with a variety of congenital factor deficiencies. It is currently being marketed by the American Red Cross.

DR-FFP is derived from volunteer blood donors and is stored in single-donor units of 225-275 mL. Donors are screened and the plasma tested for viral disease markers in the usual way. However, the plasma is released only if the donor returns after at least 90 days and again tests negative for all viral disease markers.

The safety of both S/D FFP and DR-FFP should be regarded as greater than that of untreated, nonquarantined plasma but for different reasons. S/D FFP offers the possibility of inactivating lipid-enveloped viruses that have yet to be detected or characterized as human pathogens. However, the moderately large number of donors contributing to each pool may increase the possibility of transmission of agents not

inactivated by the S/D process (such as non-lipid-enveloped viruses e.g. hepatitis A, parvovirus B19) nor by potentially neutralizing antibodies that may be present in the product. In contrast, the use of DR-FFP may limit the number of donors to which a patient is exposed but can only ensure increased safety with respect to those viruses for which serologic tests are performed.

There are no prospective clinical trials comparing the residual risks of S/D-FFP to D/R-FFP, and such studies are unlikely to be conducted because of the very large numbers of recipients that would be required. Thus, the ultimate choice between these two products is likely to depend on factors such as physician and patient preference, local availability, and cost.

Based upon all these considerations, it is the recommendation of MASAC that either DR-FFP or S/D FFP be used as plasma transfusion alternatives except in emergency situations when these products are not readily available and when delay in treatment is considered to create significant risk of harm to the patient.

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