Quality of freeze-dried (lyophilized) quarantined single-donor plasma.

Bux J, Dickhörner D, Scheel E.

BACKGROUND: Transfusion of plasma is a basic treatment for complex coagulopathies as well as in major blood loss. Early transfusion of plasma after trauma with major hemorrhage has been recommended by retrospective studies. However, the use of plasma is often hampered by the need to maintain a cold chain and the time needed for thawing fresh-frozen plasma (FFP). With freeze-dried (lyophilized) plasma (FDP) both difficulties can be avoided. Here we describe the production, quality characteristics, and our experiences with FDP.

STUDY DESIGN AND METHODS: Quarantine plasma samples were freeze-dried. The clotting factors fibrinogen, Factor (F)V, FVIII, FXI, von Willebrand factor (vWF), protein S, antithrombin, plasminogen, and plasmin inhibitor were determined after manufacturing and after storage at room temperature and refrigeration. Reported adverse transfusion events were evaluated and compared to that of FFP. Clinical effectiveness was estimated by inquiry among experienced users.

RESULTS: Lyophilization resulted in a loss of coagulation factor activity between 0% and up to 20% to 25% (FVIII, vWF). When stored refrigerated, coagulation factors did not lose more than 10% of their activities. Storage at room temperature for 24 months mainly affected vWF/ristocetin cofactor activity and fibrinogen activity. From 2007 to 2011 more than 230,000 units of FDP were delivered. There were no reports about clinical ineffectiveness. The frequency of transfusion reactions was not different from that of FFP.

CONCLUSION: Lyophilized plasma showed characteristics similar to FFP. Since FDP requires neither complex logistics nor time-consuming thawing, it allows rapid treatment of coagulopathies.