Hemorrhage Control and Resuscitation

Demonstration of Safety Analysis of Freeze-dried Plasma in Normal Healthy Volunteers

Current standard of care for hemorrhage on the battlefield involves infusion of blood components such as fresh frozen plasma (FFP) and liquid-stored platelets, which can only be stored and administered at reasonably equipped (Role of Care 3) facilities. Freeze-dried plasma (FDP) offers coagulation therapy and volume replacement for hemorrhaging patients in a logistically superior manner by virtue of its ability to be stored at ambient temperature and carried by medics into the field where it can be administered at the point of injury.

Vascular Solutions/Teleflex, the commercial manufacturer of FDP (Wayne, PA), recently completed a 24-subject Phase 1 clinical study. Three cohorts of eight healthy volunteers were infused with either one, two, or three units of autologous FDP. The cohort receiving three units of FDP also received three units of autologous FFP in a double-blinded crossover study design at a 14-day interval. All subjects were monitored at intervals up to 28 days and all were shown to tolerate the FDP infusion, with no serious adverse events and no significant treatment-related adverse events (*Cancelas et al., 2018*). Vascular Solutions/Teleflex, under a cooperative research and development agreement (CRADA) with U.S. Army Medical Materiel Development Activity (USAMMDA; Fort Detrick, MD), has recently validated a second generation lyophilization (freeze drying) bag and accompanying manufacturing process for large-scale production.

Plasma is a vital treatment for hemorrhage. This study demonstrates the safety of FDP for use on the battlefield when plasma is not available.

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REFERENCES:

Cancelas, J., Rugg, N., Nestheide, S., King, M., Snyder, M., Pehta, J. C., . . . Atkinson, A. (2018). Safety Analysis of a New Generation Freeze-Dried Plasma Product: Report of a Dose-Escalation, Phase 1 Clinical Trial. Transfusion, 58, 10a-10a.