

OPH 3, 5-3a



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Removal Of Prion (PrP) From Red Cell Concentrates (RCC) With A Prototype Of A Prion Removal Filter (PrRF)

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BACKGROUND: Prion diseases are fatal neurodegenerative diseases that affect both humans and animals including scrapie in sheep, bovine spongiform encephalopathy (BSE) in cattle and Creutzfeldt-Jakob Disease (CJD) in humans. The occurrence of a variant CJD (vCJD) in the United Kingdom together with the recent animal data and the evidence that the distribution of the vCJD may differ from the classical CJD has raised the question of the possibility of transmission of the causative agent by blood transfusion from infected individuals with no clinical symptoms of the disease. In the present study, we evaluated the use of a prototype of a new leukocyte reduction filter for the removal of infectious prion from RCC.

STUDY DESIGN: Units of whole blood (WB, 450±50) were collected from healthy volunteers into blood bags containing 63mL of CP2D anticoagulant. RCC were prepared from WB and then resuspended in AS3 additive solution according to standard blood bank protocol. Ten Percent (10%) scrapie brain homogenates (SBH) in buffered saline was prepared from brains of hamsters infected with 263K hamster-adapted scrapie (PrPsc). The SBH was clarified by ultracentrifugation and 30mL of the SBH was added into 270mL of RCC. The SBH-contaminated RCC (SBH-RCC) was filtered at room temperature with a prototype PrRF (Pall Medical, East Hills, NY). The presence of SBH in the RCC was determined before and after filtration using a Western blot assay with 3F4 and 7D9 prion specific monoclonal antibodies. In addition to the Western blot, different dilutions of aliquot of the pre and post filtration SBH-RCC were injected through the intracerebral route into scrapie susceptible hamsters.

RESULTS: Preliminary results showed removal of the PrPsc from full units of RCC to a level well below the limit of detection of the assay at 2 logs. After 13 weeks, none of the animals injected with filtered SBH-RCC have developed any clinical symptoms of the disease. The mean± sd concentration of leukocytes in the units of RCC was reduced from $2.23 \pm 1.01 \times 10^9$ to $1.59 \pm 0.59 \times 10^4$ (N=13) which is well below the FDA/AABB guideline of 5.0×10^6 leukocytes per unit of leukocyte-reduced RCC.

1101 771 - OPH-7

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CONCLUSION: The present results show that prototype of a new leukocyte reduction filter was effective in removing infectious prion from RCC below the limit of detection of Western blot assay and to date, none of the hamsters injected with filtered RCC have developed the disease. The use of this type of filter may help reduce the risk of transmitting infectious prions through blood transfusion. However, additional *in vivo* studies with RCC from scrapie infected hamsters in the clinical and pre-clinical stage of the disease are needed and are currently ongoing.