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Short Communication on Effect of Leukoreduction on Inflammation in Critically ill Dogs Receiving Red Blood Cell Transfusions: A Randomized Blinded Controlled Clinical Trial

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Short Communication

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ABOUT THE STUDY

Our study, affectionately known to enrolling clinicians as ICY POLE (Inflammatory Cytokines Prevented with blood Leukoreduction), arose as the natural progression from our previous research where we found that leukoreduction attenuated the accumulation of cytokines within bags of stored canine red blood cells [1,2]. We wondered whether this might translate to decreased post-transfusion inflammation in critically ill dogs, similar to the effect seen with leukoreduction in a pre-clinical trial of healthy dog's transfused autologous stored blood [3]. In critically unwell, anemic, and wounded dogs, Red Blood Cell (RBC) transfusions can save lives, but they are not without risk. Leukocyte count, C-Reactive Protein (CRP), Interleukin (IL)-6, IL-8, and Monocyte Chemoattractant Protein-1 (MCP-1) are a few of the inflammation biomarkers that increase post-transfusion in critically ill patients receiving allogenic RBC transfusions and healthy dogs receiving autologous RBC transfusions. Rapid transfusions responses like Febrile Non-Hemolytic Transfusion Reactions (FNHTR) are one clinical manifestation of transfusion-related inflammation. FNHTR do not pose a direct threat to life, but the physiological mechanisms that cause fever can increase metabolic demand and oxygen consumption, which can have a deleterious effect on patient morbidity. When oxygen delivery is hampered by anemia or hypovolemia, this scenario can be more harmful.

When we were designing our trial, we prioritized making the patient enrolment process as smooth as possible for our busy clinicians. We also wanted the study design to closely align with our current blood bank protocols, particularly the 'first in, first out' mandate to transfuse the oldest compatible blood in the bank. We didn't want to prioritize randomization group over bag age for blood bag choice, as that risked wasting blood products. It was through these requirements, coupled with the clinical equipoise of transfusing LR or non-LR blood and the commercial availability of identical LR and non-LR bags that we settled on randomizing the blood bags into groups rather than randomizing the patients. Using this randomization method, the clinicians who were enrolling patients found it less onerous to obtain owner consent. There were no daunting questions to field about the 'experimental blood' or the 'control blood' because the patients were always going to get the oldest bag of blood in the fridge. The owners just had to consent to have slightly larger samples of blood taken at times when blood was going to be collected anyway. Randomization of the bags rather than the patients ensured there were always both LR and non-LR bags in the bank, which meant after patients were enrolled in a group, they could continue to receive blood bags from that group as required within the 24-hour study window. Finally, blinding of the ECC clinical team was easily maintained, as the bags were created in a separate area of the hospital by people not involved with patient care, and were identical in appearance following processing.

While the wide variation in our population's baseline inflammation prevented our study from having adequate power to detect a difference between groups, we can use our data to begin to plan a future clinical trial. Using the 24-hour mean C-Reactive Protein (CRP) results and the standard deviation of 50 mg/L from the NLR group, we calculated that a clinical trial with 150 patients per study group would give 80% power to detect a difference in CRP between NLR and LR at $\alpha=0.05$. Employing the randomization protocol we used, and measuring CRP as the primary biomarker of post-transfusion inflammation, we believe a multicenter trial would be feasible to continue to investigate the question of whether leukoreduction abrogates post-transfusion inflammation.

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