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A Prospective Observational Study to Evaluate a CMV-specific Elispot Assay in Allogeneic Hematopoietic Cell Transplant (allo-HCT) Recipients: The REACT Study

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Background: CMV infection causes significant morbidity and mortality after allogeneic hematopoietic cell transplantation (allo-HCT) and is generally managed using a preemptive strategy with CMV viral load monitoring. CMV replication is primarily controlled by T-cell response which can be measured by quantifying IFN-y production. Therefore, we evaluated the role of a novel CMV-specific ELISPOT assay to predict CMV infection in allo-HCT recipients.

Material/methods: This is an ongoing, multi-center (13 sites), prospective, observational study of 244 adult CMV seropositive allo-HCT recipients. Significant CMV reactivation was defined as a positive blood PCR or antigenemia necessitating antiviral therapy according to each institutional protocols. T cell responses were serially monitored pre-, and every 2 weeks post-HCT and up to 26 weeks with an ELISPOT assay that uses CMV-specific antigens IE-1 and pp65 (T-SPOT.*CMV*, Oxford Diagnostics Laboratories®, Memphis, TN). ease copy and paste the corresponding text here

Results: Of 244 enrolled patients, 137 have completed the study at 26 weeks. Majority of the patients are white (73%), male (56%), and the median age is 56 years (22 – 80). More patients (46%) had unrelated while 36% had matched HCT. Most of the donors (55%) were CMV sero-positive. CMV reactivation occurred in 61 patients (25%). The negative predictive value (NPV) of a pp65 spot count >100 was 92% and 85% for protection from first CMV reactivation and death, respectively. A Cox Proportional Hazards Model for time to CMV event showed that a maximum pp65 >100 was an independent predictor of protection (HR 0.139; CI 0.072 - 0.270; p-value <.0001) from CMV reactivation while systemic steroid use was an independent predictor (HR 4.186; CI 1.506 – 11.633; p-value <.006) of CMV reactivation.

Conclusions: The REACT study demonstrated that pp65 counts >100 was a significant predictor of protection against CMV reactivation. After adjusting for different risk factors, pp65 >100 was significantly associated with protection against CMV reactivation while the use of systemic steroids was significantly associated with CMV reactivation. This study suggests insights into the CMV immune response which may guide personalized decisions regarding CMV management.

KM Plot – Time from HCT to CMV reactivation stratified by pp65 > 100 (high response) vs. pp65 ≤ 100 (low response); log-rank p-value = <.0001.