THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

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Abstract #2298

The ability of CMV-specific ELISPOT assay to predict outcome of low level CMV reactivation in hematopoietic cell transplant recipients

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BACKGROUND

- CMV infection causes significant morbidity and mortality after allogeneic hematopoietic cell transplantation (allo-HCT)
- Major pathway to control CMV replication:
  - CMV-specific cell mediated immunity, as assessed by T cells production of interferon gamma(IFN-γ)
  - Other cytokines

OBJECTIVE

To evaluate the ability of a *CMV-specific ELISPOT assay* to predict the outcome of *low-level CMV reactivation* in allo-HCT recipients

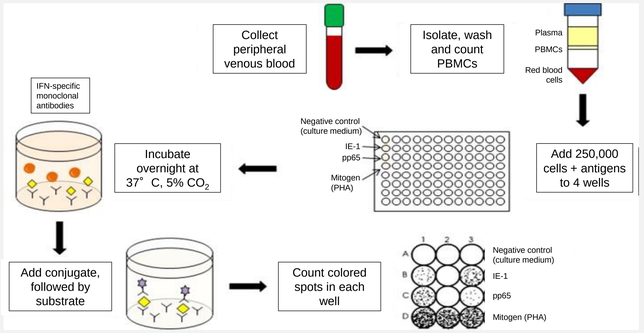
METHODS

Ongoing, Prospective, Observational study:

- Allo-HCT recipients with low level of CMV viral loads (VL) <1000 IU/ml or <500 IU/ml if they had graft-versus-host disease or were receiving systemic corticosteroids
- Weekly monitored with a CMV-specific ELISPOT assay (T-SPOT®.*CMV*, Oxford Diagnostic Laboratories®, Memphis, TN)
- Up to 8 weeks from the date of first CMV reactivation
- Data from 23 patients who reached 4 weeks of follow-up were analyzed

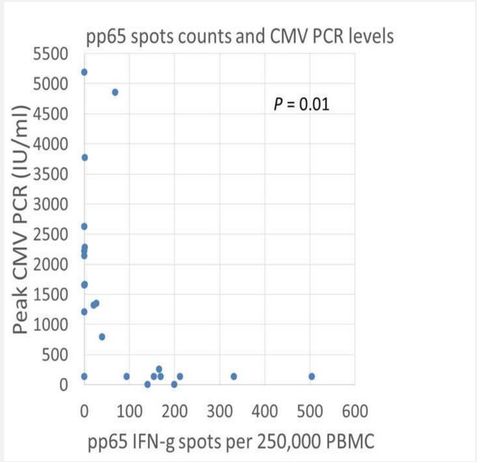
Primary endpoints: Progression from low level reactivation was defined as either ≥50% increase in CMV VL and/or CMV end-organ disease

Fig 1. CMV-specific ELISPOT assay



RESULTS

Fig 2. Inverse correlation of peak CMV VL with CMV-specific pp65 spot counts (SPC)



Mean (±SD) pp65 SPC: significantly lower in patients who progressed from low level CMV reactivation **(10 ± 20)** compared to patients who did not **(183 ± 138)**; P = 0.0003

Risk of CMV progression: Odds ratio = **1.52 (1.04 – 2.21)**, P = 0.029 for a decline of 10 pp65 SPC by next time point of measurement

Table 1. Characteristics and Outcomes of Study Participants

	Total	Progression to high CMV VL	No progression
Number of patients	23	12 (52)	11 (48)
Age (in years), median (range)	58 (18 - 68)	57 (21 – 69)	56 (24 – 73)
Sex			
Male	16 (70)	8 (67)	8 (73)
Female	7 (30)	4 (33)	3 (27)
Race			
White	10 (43)	5 (42)	5 (45)
African American	4 (17)	2 (17)	2 (18)
Hispanic	2 (9)	1 (8)	1 (9)
Other	7 (31)	4 (33)	3 (28)
Type of Cancer			
Leukemia	11 (48)	7 (58)	4 (36)
Lymphoma	7 (30)	3 (25)	4 (36)
Other	5 (22)	2 (17)	3 (27)
Type of Transplant			
Match Related Donor	7 (30)	3 (25)	4 (36)
Match Unrelated Donor	12 (52)	8 (67)	4 (36)
Autologous	4 (17)	1 (8)	3 (27)
Corticosteroid use	19 (31)	5 (22)	14 (36)
GVHD	3 (13)	2 (17)	1 (9)
HCT donor status			
CMV +	12 (52)	4 (33)	8 (73)
CMV -	11 (48)	8 (67)	3 (27)
Peak CMV VL, median (range)	1205 (137 – 5187)	2177 (1205 – 5187)	137 (137 – 790)
All-cause mortality	0	0	0

CONCLUSIONS

- Preliminary analyses showed an association between *low CMV-specific T cell responses and progression of CMV infection* in allo-HCT recipients
- *Serial monitoring of anti-CMV immune response* may help *stratify allo-HCT recipients at risk of progression* from low CMV VL to significant CMV infection, but needs further validation