Participant flow

Overall, 250 patients who experienced post-HSCT refractory, resistant, and/or an intolerant (RRI) CMV episodes (cohort 1) and 140 patients whose first post-transplant CMV episode was preemptively treated (cohort 2) were eligible for analysis as two separate cohorts.

COHORT 1

Baseline Characteristics

Patients' median age was 57 years, 50.8% were male, and 66.0% were white. Acute myeloid leukemia (39.2%) was the most common primary indication for HSCT with 49.2% of patients in complete remission and 61.2% of patients receiving treatment for the primary indication at time of transplant. The most common conditioning regimen was myeloablative (44.4%) and stem cell source was peripheral blood in 73.5% of patients. Almost half of patients (48.4%) did not receive a graft manipulation strategy. Human leukocyte antigen was matched-unrelated in the highest proportion of patients (32.7%). Donor/recipient CMV serostatus was +/+ for 55.7% of patients and -/+ for 35.2% of patients.

Outcome Measures

Median time from transplant to first RRI CMV episode was 33 days. The majority of patients (84.4%) were being preemptively treated when RRI was identified, and 88.8% had asymptomatic while 11.2% had symptomatic RRI CMV episode. Valganciclovir was used most frequently as a first-line agent (34.1%) and foscarnet as a second-line agent (47.3%). During the first RRI CMV episode, 58.0% of patients achieved clearance of CMV with a median time to clearance of 46.5 days.

CMV recurrence was 35.2%. All-cause mortality was reported in 56.0% of patients. Mortality one year after RRI identification was 45.2%. CMV-related hospitalizations were reported in 37.6% of patients (median length of hospital stay: 18 days). Most hospitalizations or emergency department visits (80.1%) were to manage RRI CMV episodes.

Adverse Events

This study did not solicit AE collection.

COHORT 2

Baseline Characteristics

Patients' median age was 57.5 years, 57.1% were male, and 45.7% were white. Acute myeloid leukemia (48.6%) was the most common primary indication for HSCT with 62.1% of patients in complete remission and 55.7% of patients receiving treatment for the primary indication at time of transplant. The most common conditioning regimen was reduced intensity (38.6%) and stem cell source was peripheral blood in 78.6% of patients. Almost two-thirds of patients (62.6%) did not receive a graft manipulation strategy. Human leukocyte antigen was matched-unrelated in the highest proportion of patients (35.0%). Donor/recipient CMV serostatus was +/+ for 68.6% of patients and -/+ for 24.1% of patients.

Outcome Measures

Median time from transplant to the start of the first post-transplant preemptively treated CMV episode was 39 days, and 97.1% of patients had an asymptomatic infection. Overall, 24.3% (n=34) of patients received anti-CMV primary prophylaxis. Valganciclovir was the most frequently used as first-line (49.3% of 140 patients) and second-line agent (46.7% of 45 patients). Overall, 81.4% of patients achieved CMV clearance during the first post-transplant preemptively treated episode, and 32.9% of patients had CMV recurrence. All-cause mortality was reported in 35.7% of patients. Mortality one year after the start of preemptively treated episode was 22.9%. CMV-related hospitalizations from first CMV episode were reported in 15.7% of patients (median length of hospital stay: 18 days).

Adverse Events

This study did not solicit AE collection.