

initiated pre-transplant in one patient, and 21 days to greater than 2 years in six patients (median of 61 days).

We analyzed 7 patients with CMV viremia who were treated under emergency IND because of lack of other reasonable therapeutic options. All 7 patients had failed conventional antiviral therapy: all patients had received ganciclovir and/or valganciclovir, 6 had received foscarnet, and 4 had received CMV IG. The doses of CMX001 in these patients ranged from 80 mg to 300 mg (approximately 2 to 4 mg/kg); follow-up data was available for at least 4 weeks in all patients. Virologic response was defined as more than a 90% reduction (1 log 10) in viral load (VL) and complete response was defined as an undetectable viral load.

The 4 males and 3 females treated had a median age of 55 years (range 11 to 69 years); they were treated with CMX001 for a median of 88 days (range 29-131 days). The median reduction in VL was greater than 1.2 log 10 at 4 weeks. A complete response was observed in 3/5 (60%) patients who did not have mutations in the CMV polymerase UL54 gene; 2/5 had an average reduction in CMV by PCR of 1.2 log 10. Neither of two patients with a relevant mutation in UL54 (L501F and A987G) had a 1 log reduction in viremia at the last time point.

Two patients had pre-existing renal insufficiency; no dose adjustment was needed based on kidney function. Four of 7 patients had GVHD during treatment with CMX001. One patient experienced *C. difficile* colitis, one experienced pancytopenia, one with a seizure disorder experienced seizure, and one experienced severe GVHD. No trends were observed in SAEs.

This case series demonstrates that CMX001 is a promising therapeutic option for the treatment of CMV disease in stem cell transplant patients.

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A PROGNOSTIC INDEX THAT PREDICTS SURVIVAL OF MECHANICALLY VENTILATED ALLOGENEIC HEMATOPOIETIC CELL TRANSPLANTATION RECIPIENTS

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Purpose: The overall outcome of hematopoietic cell transplant recipients (HCT) who require mechanical ventilation (MV) has historically been poor. However, more recent studies have shown improved survival. We evaluated the outcome of ventilated adult HCT recipients at the University of Minnesota and sought a prognostic index to predict 100 day post-MV overall survival (OS) based on factors present at the time of MV.

Patients and Methods: A retrospective study of patients ≥ 18 years of age ($n = 1557$) who received HCT at the University of Minnesota between 1998 and 2009. Patients' demographics and clinical outcomes were prospectively collected from the transplant database. Data regarding MV, organ failure and organ failure support were retrospectively collected from patients' records. 234 patients (15%) required MV in the first 100 days post HCT and were divided into a training set ($n=156$) and a validation set ($n = 78$). Multivariate Cox regression and recursive partitioning were used to build a model that classified patients into either good (class A) or poor (class B) prognostic groups. The final model was assessed in the validation set.

Results: MV occurred prior to neutrophil engraftment ($ANC \geq 500/\mu\text{l} \times 2$ days) in 94 patients (40%). 137 patients (59%) were ventilated within 30 days of HCT. The 100 day post-MV OS was 18% for the total population. Karnofsky score, serum total bilirubin and creatinine levels at time of MV, platelet count and acute GVHD were predictors of worse OS in the training set. Recursive partitioning on the training set showed that creatinine < 2 mg/dl, platelet count $> 20,000/\mu\text{l}$ and total bilirubin < 5 mg/dl at time of MV predicted a good prognostic group (class A) with 38% OS in the training set, 35% in the validation set and 37% in the total population. In contrast, the poor prognostic group (class B), had 9% 100 day OS in the training set, 7% in the validation set and 8% in the total population. Class A patients were less likely to develop kidney failure (34% versus 70%, $p < 0.0001$), require dialysis (25% versus 41%, $p = 0.0202$) and less likely to develop liver failure (5% versus 38%, $p < 0.0001$) during MV.

Conclusion: MV support is justified in HCT recipients with good prognostic features that are easily identified at the time of ventilation need. Conversely, initiation of MV is questionable for patients with poor prognostic features. For more universal use, this prognostic index requires validation at other centers and in other patient populations.

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VITAMIN D DEFICIENCY IN CHILDREN UNDERGOING HEMATOPOIETIC STEM CELL TRANSPLANTATION

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Background: Hematopoietic stem cell transplantation (HSCT) may increase the risk of Vitamin D deficiency from chemotherapy, radiation, nutritional difficulties, graft versus host disease (GVHD), restricted physical activity and limited sun exposure. Therefore, defining the extent of this problem is clinically relevant and may be therapeutically useful.

Methods: HSCT recipients, who were ≤ 18 years of age, transplanted at Duke between 01/2007 and 03/2009 and had serum Vitamin D measured, were included in this retrospective study. Total numbers of subjects satisfying these criteria were 71 (24 female; 25 non-Caucasian). Diagnoses were malignant in 39 and nonmalignant in 32 patients. Vitamin D status was defined by serum 25(OH) D2+D3 levels as follows: severe deficiency, < 10 ng/ml; moderate deficiency, 10-20ng/ml, mild deficiency, 21-30 ng/ml. Osteopenia was recorded from X-rays that were performed for any clinical reason during the study period.

Results: The median (range) age at HSCT was 6.7 years (0.1-18), weight was 29.1 kg (4-86.4), height was 117.2 cm (54-181), and post-transplant follow-up duration was 25.3 months (2.6-44.7). At transplant, 22.5% and 42% of all subjects were below 25th percentile for weight and height, respectively. Of 71 patients, 61 received myeloablative conditioning. Their median in-patient stay was 48 days (25-140). All subjects had received TPN and the median duration of TPN therapy was 64 days (range, 16-598). Overall, 46% of subjects had vitamin D deficiency during the study period (details in table). Vitamin D deficiency was present in 18 of 24 (75%) subjects with prolonged diarrhea, in 7 of 11 (64%) subjects on pancreatic enzyme therapy, in 13 of 27 (48%) subjects with chronic GVHD, and in

Table 1. Serum 25 (OH) D2+D3 Level in ng/ml

	0 - < 12 month Post-Tx (n=62)	12 month Post-Tx (n=36)	24 month Post-Tx (n=39)	36 month Post-Tx (n=16)
Severe Def. (<10)	0	0	0	0
Moderate Def. (10-20)	16 (25.8%)	6 (16.6%)	4 (10.3%)	3 (18.8%)
Mild Deficiency (21-30)	22 (35.4%)	7 (19.4%)	10 (25.6%)	3 (18.8%)
Sufficient Level (>30)	24 (38.7%)	23 (63.8%)	25 (64.1%)	10 (62.5%)

Tx, Transplant; Def., Deficiency.

21 of 38 (55%) subjects with serum albumin < 2.5 gm/dL. Osteopenia was seen in 32 (45%) subjects, half of whom had Vitamin D deficiency.

Conclusions: Vitamin D deficiency is prevalent in pediatric patients undergoing HSCT. Serum levels should be checked prospectively before and after transplantation, treatment should be administered for low levels and the clinical impact should be further studied.

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INCIDENCE AND RESPONSE TO TREATMENT OF ADENOVIRUS (ADV) INFECTION WITH CIDOFAVIR (C) IN PEDIATRIC PATIENTS AFTER ALLOGENEIC HCT

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ADV infection occurs frequently and has a high mortality after HCT. The antiviral cidofovir has activity against ADV, but has significant renal and marrow toxicity. We report our centers incidence of ADV and its association with type of transplant and GVHD (clinically significant requiring > 1 mg/kg solumedrol for at least 2 weeks). Between August 2002 and June 2010 76 patients received