ical diseases by using TEE and to assess if the D-dimer test can predict the presence of a central venous catheter-related thrombus. We assessed 37 patients with various hematological diseases (18 AML, 8 NHL, 6 ALL, 2 MM, 1 HL, 1 primary amiloidosis, and 1 MDS). Mean age was 37 years. Mean time with catheter was 2.66 months. Fourteen of thirty-seven patients were transplanted. Thrombus was found in 8 of 37 patients (21.6%). Thrombus incidence in transplanted group was 28.57% (4/14). Thirty-four of the patients (91.9) were asymptomatic. No relation was found between thrombus and D-dimer levels (P = .071). The time with catheter was not related with the presence of thrombus also (P = .328). Our findings showed that TEE is a useful method in evaluating the presence of thrombus at the tip of central venous catheters, so it can be useful for the prediction of complications due to thrombus before catheter removal. D-dimer shows tendency to be useful in predicting the presence of a thrombus.

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ATYPICAL MYCOBACTERIUM INFECTIONS IN PEDIATRIC PATIENTS UNDERGOING RELATED DONOR HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT)

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Atypical mycobacterium infections are uncommon in children undergoing HSCT compared to solid organ transplant recipients or HIV patients, though more prevalent than in the general population. Improvements in laboratory diagnostic methods have led to more accurate and timely identification of mycobacterium isolates. Diagnosis of non-tuberculus mycobacterium (NTM) infection in immunocompromised children is difficult due to non-specific, diverse clinical manifestations. We report 3 pediatric patients who underwent related donor HSCT from 2002 to 2005 and developed definite NTM infections in the setting of fever of unknown origin. Patient 3 was transplanted at Fred Hutchinson Cancer Research Center, received donor lymphocyte infusion at CMH and was re-grafted at Washington University Medical Center. CD4 counts were >200/μl at the time of diagnosis. Of note, the CD4 count had just recovered in patient 2 as has been reported in patients with AIDS developing atypical mycobacterium osteomyelitis. All patients were immunosuppressed at the time of NTM diagnosis. Aggresive local treatment such as debridement followed by bone grafting and insertion of appropriately coated antibiotic beads was essential for treatment of NTM osteomyelitis. Patient 3 underwent a second transplant and an alemtuzumab-based reduced intensity conditioning regimen without NTM prophylaxis and did not reactivate infection. Outcomes of NTM disease were all favorable after appropriate antimicrobial therapy. Susceptibility testing of isolates with MIC was very helpful in choosing appropriate outpatient treatment. The combination of newer macrolides, ethambutol, rifabutin, and fluoroquinolones appears to have greater in vivo activity and to provide improved eradication of bacteria compared to single agents. Concomitant surgical debridement and removal of the central venous catheter when indicated was essential. We conclude: (1) NTM infection can cause fever of unknown origin in HSCT patients. (2) NTM infection can be successfully treated in the outpatient clinic with antimicrobials chosen according to susceptibility testing of patient isolates. (3) Local treatment such as catheter removal, excisional biopsy, and surgical debridement are critical and can be performed without delayed wound healing or the necessity of skin grafting in the setting of active skin GVHD. (4) Subsequent second HSCT can be performed without prophylaxis provided that the prior NTM infection has been adequately treated (Table 1).

Table 1. *Patient Characteristics and Outcomes*

Category	Pt. 1	Pt. 2	Pt. 3
Diagnosis	SCID	AML	IPEX
Age at HSCT	6 months	16 years	2 years
Stem Cells and Match	maternal PBSC, 3 of 6	maternal PBSC, 3 of 6	BM, 6 of 6 sister
Preparation	Flu/ATG	Flu/TBI/Melphalan/ ATG	1: Flu/TBI; 2: Campath/Flu/ Melphalan
GVHD prophylaxis/ treatment	TCD	TCD	1: Tacrolimus, MMF; 2: Tacrolimus, steroid
Vital Status	alive	alive	alive
Engraftment	full donor chimerism	full donor chimerism	1: mixed chimerism; 2: mixed chimerism
GVHD	grade II acute	grade II acute	none
A. Mycobacterium site	central line, lung	tibia	subcutaneous
Species	M. chelonae/ abscessus	M. avium complex	M. chelonae/abscessus
Evaluation	blood culture, CT scan, lung biopsy	CT scan, MRI, bone aspiration	CT scan, MRI, excisional biopsy
Onset	+6 months	+39 days	+22 months
Treatment & Outcome	catheter removal, ciprofloxacin, azithromycin, linezolid × 6 wks; resolved	azithromycin, ethambutol, linezolid × 8 months, debridement, bone graft with antibiotic beads	surgical excision; cefoxitin, azithromycin, linezolid × 8 months

Abbreviations: SCID, common gamma chain X-linked severe combined immunodeficiency; AML, acute myelogenous leukemia; IPEX, immune dysregulation, polyendocrinopathy, enteropathy, X-linked; PBSC, peripheral blood stem cells; BM, bone marrow; Flu, fludarabine; ATG, anti-thymocyte globulin; TBI, total body irradiation; TCD, T-cell depletion; MMF, mycophenolate mofetil

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A PHASE I SAFETY, TOLERABILITY, PHARMACOKINETIC, AND PHARMACODYNAMIC ASSESSMENT OF VELAFERMIN IN PATIENTS WITH ACTIVE ORAL MUCOSITIS

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Velafermin (CG53135-05) or recombinant human fibroblast growth factor-20 (rhFGF-20) protein is under investigation for the treatment of active oral mucositis (OM). OM is a commonly occurring side effect of high-dose chemotherapy (HDCT) in patients (pts) undergoing autologous hematopoietic stem cell transplant (AHSCT) and in leukemia pts receiving CT. Pharmacology studies demonstrated that treatment of velafermin to animals with active OM for 2, 3, or 4 consecutive days resulted in a significant reduction in duration of clinically relevant OM compared with animals in the vehicle treated control group. Previous clinical studies showed that velafermin was generally well tolerated as a single dose regimen up to 0.2 mg/kg dose level. The objectives of this Phase I trial are to evaluate the safety, tolerability and pharmacokinetics (PK) of velafermin when administered as three daily doses via intravenous (IV) infusion to pts who develop oral mucositis after receiving HDCT. OM and diarrhea status are evaluated using the World Health Organization (WHO) grading system. Approximately 9–12 pts receiving AHSCT following myeloablative CT or leukemia pts receiving CT, age 18 years and older, are to be enrolled when Grades 1 or 2 OM is observed. Velafermin treatment is initiated within 24 hours after OM is observed. Three pts will be treated at each dose level based on tolerability and recruitment parameters. Pts will receive velafermin at 0.03, 0.1, or 0.2 mg/kg/day for 3 consecutive days. Pt follow-up will be continued for approximately 60 days following infusion of velafermin. The 3 pts in the first cohort receiving 0.03 mg/kg tolerated multiple doses of velafermin well with no complaints or adverse events (AE) during or immediately after infusion. Dose escalation deci-

sion was made at 14 days after pts completed velafermin administration with no dose limiting toxicity reported. All abnormal hematology or chemistry laboratory reports were expected and consistent with pt disease conditions. The second cohort of 0.1 mg/kg dose is ongoing with 2 pts completed study drug infusion. The safety profile and clinical data of all pts will be reported.

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CAREGIVER SUPPORT GROUP ON PEDIATRIC BONE MARROW TRANSPLANT UNIT: WHAT FAMILIES ARE TALKING ABOUT AND WHY THE MEDICAL TEAM SHOULD LISTEN

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Prompted by families' unrest in the Pediatric Blood and Marrow Transplant Unit at Cincinnati Children's Hospital Medical Center, in the Spring of 2005, social workers began an hour-long, weekly support group for caregivers of inpatients. Group attendance has depended upon unit census and other factors such as caregivers' ability to leave the child in the room with an attendant. Notable discussion points have emerged and the group has become not only a support for caregivers but a guide for the medical team on how to best assist families and patients through treatment and recovery. The team's understanding of the main, or previously unrecognized, family issues is resulting in a better outcome for the patients and caregivers. Overt and covert topics have emerged from the group. Overt topics, or those "on the surface" or "expected" to appear, remain consistent within almost each discussion. These explicit topics include difficulty with distance from primary residence and managing the household, benefit in connecting with other caregivers on the unit, balancing siblings' needs while caring for sick child, and financial strain. While it is necessary for the medical team to be mindful of those struggles, it is potentially even more important to consider covert issues that also make a powerful impact and often go unnoticed. Covert topics, or those not as readily voiced but shared among caregivers, may include self-care and the need to be away from the child to express emotions, responding to emotionally "needy" families on the unit, physical impact of illness on the patient, fear of returning to hospital following discharge, neediness of the ill child, comprehending medical information and advocating for the child with the medical team, how to successfully convey concerns to the team, and a repeated expression in confidence of the medical facility (potentially stated for their own reassurance). In creating a safe environment for caregivers to share their concerns, struggles, and joys, the medical team gains a better understanding of how to interpret caregivers' behavior and respond within a family-centered care model. Subsequently, the patient's treatment and recovery may go more smoothly with families feeling better supported. Acknowledging the multitude of strains and adjustments that accompany a prolonged hospitalization will benefit all involved with the patient's care and, ultimately, the patient.

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GLUTAMINE SUPPLEMENTATION TO REDUCE ORAL MUCOSITIS IN MULTIPLE MYELOMA PATIENTS RECEIVING HIGH-DOSE MELPHALAN AND AUTOLOGOUS STEM CELL TRANSPLANTATION: A FEASIBILITY STUDY

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Oral mucositis is a common and distressing toxicity associated with high dose Melphalan (HDM) and autologous stem cell transplantation (ASCT). The amino acid, glutamine (GLN), has been employed in an attempt to ameliorate oral mucositis in various high dose chemotherapy regimens with mixed results. This pilot study sought to evaluate the feasibility of administering an oral GLN food supplement in patients with multiple myeloma undergoing HDM and ASCT. Twelve patients (3 females and 9 males), median age 51, consented and enrolled in the trial. GlutaSolve™ (Novartis) 15 gm bid was administered 4 days before the start of HDM and continued for at least 14 days or 28 doses. Oral assessment and mucositis ratings were scored by trained oncology nurses and physicians using the NCI Common Toxicity Criteria, version 3.0. Compliance with bid dosing, tolerance of GLN, pain medication usage, total parenteral nutrition (TPN), and hospital length of stay (LOS) were measured. The 12 study patients were compared to case controls matched by gender, age, and presence or absence of renal dysfunction. **Results:** The compliance rate for planned GLN doses was 91.3 %. Toxicities were minimal and were limited to occasional nausea, vomiting, and mild abdominal pain after taking GLN. Several patients developed aversion to ingesting GLN toward the end of the treatment period. There were no cases of clinical grades 3 or 4 oral mucositis observed in the 12 study subjects. Median clinical mucositis score was grade 1 (mean = 1.2) and median functional mucositis score was grade 1 (mean = 1.1). Control patients had median clinical and functional mucositis scores of 2 (mean = 1.5) and 1 (mean = 1.25), respectively. Only 1 study patient developed functional grade 3 mucositis (unable to adequately aliment or hydrate orally), whereas 3 control patients experienced grade 3 mucositis. None of the study patients received TPN and only 1 patient received parenteral analgesia for oral discomfort. In comparison, 2 controls received TPN due to oral mucositis and 4 received parenteral analgesia. Average LOS was 16.8 days for study patients and 17.4 days for controls. **Conclusions:** Oral GlutaSolve™ supplement is safe and well tolerated in patients receiving HDM and ASCT for treatment of multiple myeloma. Results of this pilot study suggest this inexpensive form of GLN may reduce the severity of oral mucositis and further study is warranted in patients receiving HDM and ASCT.

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ANTIBACTERIAL PROPHYLAXIS DURING NEUTROPENIC PHASE IN AUTOLOGOUS PERIPHERAL BLOOD STEM CELL TRANSPLANT (APBSCT). COMPARISON BETWEEN CIPROFLOXACIN + AMOXICILIN VS. LEVOFLOXACIN

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From November 2002 to May 2004, the patients who received an APBST had a prophylactic antibacterial regimen with ciprofloxacin 500 mg PO BID + amoxicilin 500 mg PO TID (group A). After June 2004 our protocol changed to levaquin 500 mg PO daily (group B). We compared the incidence of fever, infections, and mortality related to the infections in these 2 groups. All the patients were in an individual room and they received filgrastin from day +7 until neutrophils recovery. In case of fever a complete physical exam, blood and urine cultures, and chest X-Ray were done, and a Carbapenem was started. There were 20 patients in group A, 13 men and 7 women, median age 38.90 years (15–67); 6 HD, 7 MM, 7 NHL. The average time with neutrophils <500 was 9.4 days and for engraftment was 11.4 days. Sixteen of twenty had fever (80%), in 7 (43.7%) the cause was unknown, in 5 (31.2%) a bacteria was found (*E. coli* [3], *S. epidermidis*[2]); 1 patient had pneumonia caused by *A. fumigatus*, and 3 had engraftment syndrome and there were no deaths. Group B were 19 patients, 12 men and 7 women, median age 50.5 (24–60), 10 MM, 5 NHL, 4 HD. Average time with neutrophils <500 was 9.47 days (7–12) and for engraftment was 11.42 days (11–14). Seventeen patients had fever (89.4%): 12 (70%) of unknown cause, in 3 (17.6%) a bacteria was found (*Burkhordelia cepacea* [1], *E. coli* [2]), 1 had engraftment syndrome and 1 pneumonia without germ. We had no deaths due to infection, and 1 patient died secondary to VOD. For comparing the groups a Fisher's test was done, and there were no significant differences in frequency of fever cases ($P = .365$) nor bacteremia cases ($P = .378$). These results remained non significant after adjustment with a logistic model for neutropenia days and the average of days for engraftment between the groups; Wald test for fever $P = .578$ and for bacteremia, $P = .370$. The prophylaxis daily