OVERCOMING LOGISTICAL CHALLENGES IN PERFORMING INTERVENTIONAL CLINICAL TRIALS IN THE LONG-TERM FOLLOW-UP (LTU) SETTING AFTER HEMATOPOIETIC CELL TRANSPLANTATION (HCT)

Dahlgren, C.J., Nguyen, H.-L., Choe, P., Beeck, M. Fred Hutchinson Cancer Research Center, Seattle, WA.

Background: Conducting interventional clinical trials according to Good Clinical Practice (GCP) standards presents a formidable challenge in the LTU period following HCT. Challenges include receiving blood specimens promptly from patients living in remote locations, gaining patient and provider commitment to regular lab testing and clinical assessments, and maintaining timely communication between providers and patients for clinical interventions.

Methods: We evaluated logistical aspects of conducting an interventional clinical trial in the LTU setting. Data from a multicenter, randomized placebo-controlled trial for prevention of late CMV complications were examined for: geographic distribution of patient location, feasibility of overnight shipment of specimens, and time to appropriate intervention following results. Clinical interventions consisted of (a) start of preemptive antiviral treatment for positive CMV quantitative PCR result (b) interruption of study drug administration and start of GCSF for any neutropenic episode defined by ANC <1.000/uL and (c) adjusting dose of study medication based on renal function. The study included 8 participating sites. All samples were analyzed at FHRC, the central site.

Results: 140 study participants were distributed over 112 cities and 36 states including Alaska. We received 3661 blood specimens (90% were collected at off-site locations). From the time each specimen was sent by overnight carrier, 85% were received by the central site in <24 hours, 9% were received between 24-48 hours, and 6% were received >48 hours. Treatment for CMV began after a median of 1 (range 0-7) day(s) after the PCR result was obtained. Upon report of the CMV PCR result to the provider, 26% of patients were treated on the same day, 37% within 1 day, 26% within 2 days, and 11% within 3 days. The median time from awareness of neutropenia to holding study drug was 0 (range 0-3) days; 81% of the patients held study drug on the same day of the result, 5% within 1 day, 11% within 2 days, and 3% within 3 days. Dose adjustment for renal function was implemented a median of 1 (range 0-2) day(s) upon obtaining the result. Of these renal adjustments, 2% occurred on the same day, 95% within 1 day, and 3% within 2 days. Conclusions: This study demonstrates that complex interventional randomized studies in the LTU setting are feasible, even if most participants live in distant locations, and that therapeutic decisions can be made on a real-time basis.
ing their unfamiliarity with this new method of stem cell mobilization. The patients appreciated the inpatient RN’s assistance and this protocol but were initially dissatisfied with the lack of privacy on a busy inpatient unit. A private area on the inpatient unit was later secured for study patients to be assessed and monitored. The administration schedule created some frustration on the part of the patients due to the long delay between study drug injection and apheresis. Nevertheless, accrual to this trial at our institution has been relatively brisk. Patient education, nursing coordination, and collaboration with members of the BMT team were paramount in our successful implementation of this study. Designated nursing staff committed to clinical trials, as well as detailed, mandatory inservices need to occur in order to implement a complex BMT trial such as this. Our experience with this trial leads us to conclude that in order to determine whether patients may benefit from novel BMT strategies, effective nursing teamwork, education, and collaboration will be essential.

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REDUCING ADMISSION RATES POST-STEM CELL TRANSPLANT UTILIZING AN EDUCATIONAL QUESTIONNAIRE TO ASSESS RETENTION OF CAREGIVER KNOWLEDGE
Chadakhtzian, A., Barnes, Y., Hayashi, R.J., Shroyer, S. 1. Saint Louis Children’s Hospital, Saint Louis, MO; 2. Washington University School of Medicine, Saint Louis, MO.

Background and Aim: Caregivers and recipients of stem cell transplants (SCT) undergo an educational process to understand, anticipate, prevent, and seek appropriate intervention for transplant related medical and social issues. A quality assessment questionnaire was developed to assess retention of pediatric SCT discharge education. The aim was to (1) determine the feasibility of administering a quality assessment questionnaire following SCT education to caregivers in pediatric SCTs and (2) correlate administration with re-admission rates in the first 100 days post SCT.

Methods: The questionnaire was randomly introduced to a group of 3 caregivers prior to discharge. Twelve non-consecutive caregivers served as the control group. The questionnaire comprised of 10 multiple-choice questions for autologous and 15 for allogeneic patients. Questions were directed at recalling the education they received. Upon completion, all answers were reviewed with the caregiver(s). Any incorrect answers were reviewed and the correct answer and rationale provided. Re-admission rates were monitored in both groups for the first 100 days. Results: Twenty-five patients (12 control; 13 test subjects) were analyzed during a 17 month period, March 2004 to July 2005. Compliance was 100% in the test group. Patient age ranged from 19 months to 17 years; there were 18 males and 7 females. The test group consisted of 2 autologous PBSC (peripheral blood), 2 MSD (matched sibling) BMT, and 5 URD (unrelated donor) BMT. The control group consisted of 2 autologous PBSC, 5 MSD PBSC, and 5 URD BMT. The test group re-admission rate was 5/13 (38%). The control group re-admission rate over the same period was 9/12 (75%). Staff variables between the 2 groups were similar.

Conclusions: Utilization of this tool decreased the incidence of re-admission. This study suggests there is value in development of a quality assessment tool assessing the impact of transplant related education for patient caregiver(s) prior to discharge. There is a trend toward decreased re-admissions in the early post-transplant period and may translate into less cost, better care and comfort for the patient. Continued assessment of this in a larger cohort is planned over an extended period to determine the benefits of this tool.

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RECOGNIZING INDICATIONS FOR PHOTOPHERESIS IN ACUTE AND CHRONIC GRAFT-VERSUS-HOST DISEASE PATIENTS

Introduction: Extra Corporal Photopheresis (ECP) is currently being used as an effective treatment for patients with Acute and Chronic Graft-versus-Host Disease (GVHD). Treatment has been initiated as early as 24 hours post transplant (1). Treatment of the Graft-versus-Host Disease to be refractory to corticosteroids. Although there is no standard treatment for Chronic Graft-versus-Host Disease, ECP has been utilized as treatment with promising results. Methods: Cumulative treatment records for patients with Acute and Chronic Graft-versus-Host Disease that received photopheresis were retrospectively reviewed. Indications, frequency, and appropriateness of photopheresis treatment were analyzed. Although there were indications of improvement in patients with Acute and Chronic Graft-versus-Host Disease while receiving photopheresis treatments, it was difficult to quantify positive or negative changes in the patients’ physical assessment. It is important to recognize early indications of Graft-versus-Host Disease in the allogeneic blood and marrow transplant (BMT) population. Presented is an assessment tool to facilitate recognition and follow-up of physical indicators in patients with Acute and Chronic Graft-versus-Host Disease (GVHD). This assessment tool was developed following discussions with physicians and nurses in an effort to prospectively quantify the response to therapeutic modalities. Additionally, this tool will assist in identifying time of response and benefits of treatments. This tool is being validated prospectively on patients currently undergoing ECP. Once validated, the instrument will be placed in routine use. The ultimate goal is to develop a tool to assist the clinician in providing an initial and ongoing physical assessment both before and during photopheresis treatment. This tool can assist in identifying improvements or changes in the patient’s Acute or Chronic Graft-versus-Host Disease status.

Results and conclusion will be presented.

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PERIPHERAL BLOOD CD34+ ENUMERATION AS PREDICTOR FOR AUTOLOGOUS HEMATOPOIETIC PROGENITOR CELL (HPC) COLLECTION IN CHILDREN
Daum, C.D., Klinger, E.F., Nendorf, S.M., Shao, V., Nourani, A., Caucabia, C. Children’s Hospital of Orange County, Orange, CA.

Purpose: The ability to accurately predict the collection of adequate numbers of CD34+ cells in children can minimize the unnecessary placement of apheresis catheters and stem cell collections. We hypothesize that the numbers of peripheral blood CD34+ cells will predict successful collection of HPCs in children and are a more accurate predictor of successful collection than white blood count. Methods: We studied 28 potential candidates for autologous stem cell transplantation. Diseases included neuroblastoma (n = 7), medulloblastoma (n = 8), acute leukemia (n = 4), acute promylcyeotic leukemia (n = 1), other solid tumors (n = 8). The age range of the patients was 11 months–20 years. All received chemotherapy followed by 10 mcg/kg/day G-CSF (24), or GM-CSF (1), or G-CSF + GM-CSF (2), or G-CSF + IL-11 (1). Peripheral blood counts were monitored a minimum of twice weekly. When the WBC > 1000/ul, peripheral blood CD34+ cells were enumerated by flow cytometry. Apheresis was initiated when the peripheral blood CD34 count was > 10/ mm3. Apheresis was performed with the goal of collecting 5 x 10^6 CD34+ cells/kg. Results: Twenty-two of 28 patients had > 10 CD34+ cells/ul prior to apheresis. Three patients had CD34 counts between 5–10/ul and 3 patients had CD34 counts > 5/ul. The median CD34 count for all patients was 21,000/ul (range 2–215,000/ul). Twenty-one of 22 patients with > 10 CD34+ cells/ul had > 10 x 10^6 CD34+ cells/kg collected and one patient reached 4.8 x 10^6 CD34+ cells/kg after 2 collections. Patients with > 10 CD34+ cells/ul required a mean of 1.41 collections to reach the goal of 5 x 10^6 CD34+ cells/kg. All patients whose CD34+ count was > 1 achieved their target goal of 5 x 10^6 CD34+ cells/kg in a mean of 3.33 collections. Only 1 of 3 patients with < 5 CD34+ cells/ul reached the goal of 5 x 10^6 CD34+ cells/kg although in all 3 cases, > 1 x 10^6 CD34+ cells/kg were collected. Twenty-eight of 28 patients had a WBC > 1000/ul prior to collection and the WBC did not correlate with the numbers of circulating CD34+ cells. Conclusions: We found that starting apheresis when the CD34+ cell count was 10 consistently resulted in meeting the target goal of collecting > 5 x 10^6 CD34+ cells/kg and that