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THE EFFICACY OF ORAL GLUTAMINE AS A PRELOADED MEDICINE IN REDUCING THE SEVERITY AND DURATION OF MUCOSITIS IN THE PEDIATRIC STEM CELL TRANSPLANT SETTING

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Objectives: (1) To compare the severity and duration of mucositis during myeloablative hematopoietic stem cell transplant (HSCT) in patients receiving glutamine starting 2 weeks prior to preparative therapy vs. historical controls using standard mouth care without glutamine. (2) To determine the feasibility of preloading glutamine in pediatric patients.

Background: Mucositis is a highly debilitating complication of myeloablative HSCT. It is associated with pain, poor oral nutritional intake, diarrhea, and increased risk of infections due to poor mucosal integrity. A randomized, placebo-controlled pediatric trial demonstrated decreased mucositis scores, narcotic use, and days of TPN with glutamine supplementation beginning with HSCT preparative therapy (Aquino, VM (2005) a pediatric blood and marrow transplant consortium study. *Bone Marrow Transplant* Oct 36;611–6). Based on the results of that trial and the mechanism of action of glutamine, we tested the feasibility and efficacy of starting glutamine supplementation 2 weeks prior to the preparative regimen.

Methods: The glutamine group (N = 25, sequential patients) received 2 grams/m2 qid swish and swallow of glutamine (500 mg/ml suspension) for 14 days prior to and throughout HSCT admission. The historical control group (N = 25, sequential patients) received standard mouth care without glutamine beginning on admission for HSCT. Data was obtained from retrospective chart review. Outcome measures include days of TPN, days of intravenous narcotics, length of hospital stay, and mucositis scoring.

Results: All patients preloaded with glutamine completed 14 days. Analysis of the historical control group showed a mean of 36 days of TPN use , a mean of 28 days of narcotic use, a mean of 49 days of hospital stay and a mean mucositis score of 3. Data collection for the glutamine group and the statistical analysis will be completed in November.

Conclusions: Pediatric patients were able to complete 14 days of glutamine prior to HSCT admission. We will report the efficacy of glutamine compared to the historical control at the meeting. If the glutamine group has decreased morbidity during HSCT (measured by mucositis scores, days of narcotics, days of TPN, length of stay), we will test the efficacy of the preloaded glutamine vs. glutamine started concurrently with preparative therapy in a prospective randomized trial.

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LONG-TERM FOLLOW-UP OF PATIENTS AFTER ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT) WITH REGARD TO QOL AND SOCIAL FUNCTIONING IN CHRONIC GVHD: A SINGLE-INSTITUTE ANALYSIS

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Purpose: A single-institute evaluation of patients who underwent allogeneic HSCT with regard to QOL, social functioning and chronic GVHD was performed to identify a suitable long-term follow-up system that is compatible with the Japanese medical environment and society.

Methods: The subjects were patients who underwent myeloablative allogeneic HSCT at our institute between January 1999 and December 2007, and who were still surviving disease-free. Chronic GVHD was evaluated by each attending physician with the use of NIH-GVHD. QOL was self-recorded by the patients according to SF-36 ver2.0, FACT-BMT and FACIT-Sp12. Changes in social function were evaluated in terms of the working status as a landmark. This study was approval by the IRB and consent was obtained from all patients.

Results: During the study period, a total of 52 patients met the enrollment criteria and complete data were obtained from 50 patients (96.2%) for the analysis. There were 23 males and 27 females (median age, 41 years; range, 19–56 years), with a median follow-up of 3.6 years (0.5–8.9 years). Twenty-one patients underwent related PBSCT and 29 patients underwent BMT (related 4, unrelated 25). Chronic GVHD was observed in 40 patients, with an average NIH-GVHD score of 3.6 (0–13), predominantly in the mouth and eyes. Patients who had scores of "none" or "mild" were classified as the "observation group" (23 patients, 46%), while those with "moderate" and "severe" findings were classified as the "treatment group" (27, 54%). With regard to QOL, all of the average SF-36 subscales were below Japanese standards. The median period required to return to their original job was 12 months (2–24 mo), and 12 patients (24%) had variable changes in the labor status, which were significantly related to the degree of NIH-GVHD. Factors that significantly affected the changes in labor status and degree of NIH-GVHD included 1) "physical functioning", "general health perceptions" and "social functioning" for SF-36, 2) "total score", "functional well-being", "emotional well-being" and "BMT-score" for FACT-BMT, and 3) "total score" and "meaning/peace" for FACIT-Sp12.

Discussion: This study confirmed that NIH-GVHD may be useful in the initial risk-adjusted stratification of patients for subsequent psychosocial/spiritual follow-up and intervention in a country which has different clinical manifestations of GVHD and a different medical/social environment than in the US.

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STORIES AND MUSIC FOR ADOLESCENT/YOUNG ADULT: RESILIENCE DURING TRANSPLANT

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Adolescents and young adults (AYA) have unique concerns and needs compared to older adults undergoing Stem Cell Transplant (SCT). A randomized clinical trial is underway to determine if the development of a Therapeutic Music Video (TMV) can help AYAs (ages 11 to 24) gain resilience as an outcome of SCT. Resilience is defined as positive adjustment in the face of adversity. The study's conceptual model identifies resources such as family environment, adaptive coping, and social support that interact to decrease defensive coping, symptom distress, and uncertainty. The TMV intervention may help AYAs undergoing SCT use music and lyrics as a way to reflect on and work through cancer related distresses. The major hypotheses of this study are that when compared to the low-dose control, study participants who receive the TMV will have decreased uncertainty and symptom distress and increased family adaptability/cohesion and communication, perceived social support, adaptive coping, hope, spiritual perspective, resilience and quality of life. This study, administered from Indiana University, is a cooperative effort among 3 adult and 6 children's hospitals at 6 medical centers across the country. Currently 80 AYA undergoing SCT have been enrolled in the study; the target sample is 175. Participants are randomized to the TMV or audio books condition. Regardless of group assignment, over a 3week time period, participants have 6 one-hour meetings with a board-certified music therapist. With help from trained evaluators, participants also complete QOL questionnaires accessed through secure web-sites on laptop computers. In the adult setting, clinical trials of behavioral interventions targeting young adults (YA) are rarely done. There are both challenges and benefits to conducting such studies in adult hospitals. For example, AYA who are married or have children are not eligible for the study, because their illness related concerns may be very different. A benefit is access to the resource of a board-certified music therapist, which may not be as readily available in adult hospitals; both staff and the AYA patients have enjoyed the addition of music therapy and staff have gained opportunities to understand this patient population through their

sharing of their TMV projects. This study is funded by the National Institutes of Health, National Institute of Nursing Research R01 NR008583 and by Children's Oncology Group ANUR0631.

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PSYCHOSOCIAL ADJUSTMENT IN LONG TERM SURVIVORS OF ALLOGENEIC HSCT: A COMPARISON OF PATIENTS TREATED WITH MYELOABLATIVE (MC) AND REDUCED INTENSITY CONDITIONING (RIC) REGIMENS

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Background: Long term survivors of allogeneic HSCT (aHSCT) may experience significant psychosocial distress. Although factors predicting increased distress have been reported, the influence of conditioning intensity has not been explored.

Purpose: This analysis compares the psychosocial (PS) adjustment of long term survivors who received RIC (n = 43) or MC (n = 77) regimens and examines predictors of PS adjustment and its relationship with health-related quality of life (HRQL).

Methods: Cross-sectional data were drawn from an ongoing longitudinal study. Measures included the Psychosocial Adjustment to Illness Scale (PAIS), the Rotterdam Symptom Checklist-physical (RSCL-P) and the Functional Assessment of Cancer Therapy – General (FACT-G). Data were analyzed using descriptive statistics, correlation and regression analyses.

Results: Subjects (N = 120) were a median of 62 months from aHSCT (range 34–156), predominantly male (59%), married (63%), and had an ECOG status of 0 (86%). Mean scores for PS adjustment did not differ between the RIC (27.6±2.56) and MC (26.1±1.82) groups ($t = 4.93$, $p = 0.62$). Age, gender, marital status, education, employment, transplant conditioning intensity, performance status and physical symptom distress explained 50.5% of the variability in PAIS scores (F = 9.30, $p<0.01$). Being unmarried ($\beta = -0.169$, $p = 0.044$) and experiencing greater physical symptom distress ($\beta = 0.609$, $p<0.001$) independently predicted poor adjustment. Poor PS adjustment was strongly associated with poor HRQL (r = −0.78, p<0.001). Survivors (n = 29; 24%) with poor adjustment (PAIS T-score ≥62) reported the greatest difficulties with family (immediate and extended) issues, sexual relationships and psychological distress.

Conclusion: Understanding the factors that predict poor PS adjustment in survivors of aHSCT guides assessment strategies including approaches to systematically assess and manage distressing symptoms. Studies to develop and test educational and counseling interventions that optimize individual and family functioning, including sexual relationships, in transplant recipients are warranted.

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IMPLICATIONS FOR NURSES AND THE SUPPORTIVE CARE NEEDS FOR CHILDREN UNDERGOING REDUCED INTENSITY CONDITIONING (RIC) ALLOGENEIC STEM CELL TRANSPLANTATION (RIC-ALLOSCT)

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Allogeneic hematopoietic stem transplant (AlloSCT) is a curative option for many children with malignant and non-malignant disorders. However, myeloablative AlloSCTs are associated with 20–40% non-relapse related mortality (NRM) in first 100 days post AlloSCT (Satwani/Cairo et al, BBMT 2005, PBC 2007). The morbidity and mortality associated with AlloSCT often result in an increase in length and complexity of nursing care. However, RIC-SCT may potentially reduce toxicities and lead to a reduction in supportive care needs associated with an increase in nursing care; including reduction of blood products, antibiotics, TPN, and narcotics. There is limited data on the toxicities of RIC-AlloSCT in children and the impact on their nursing needs. We evaluated the toxicities and supportive care measures during the conditioning regimen and 30 days post transplant required in 43 children who underwent a RIC-AlloSCT between January 2004-March 2008 for either a malignant (n = 23) or non-malignant disease (n = 21): Median age 10yrs (0.3- 22yrs), UCB (n = 17), MFD (n = 20), MUD (n = 6). Average risk patients (n = 41), poor risk (n = 2).

Regimens: Busulfan(6.4–8mg/kg)+Fludarabine(150–180mg/m^2) ± ATG(8mg/m^2) (n = 22); Cyclophospamide(60mg/kg)+Fludarabine + (150mg/m^2) ± ATG(8mg/m^2) (n = 10); Busulfan (12.8–16mg/kg)+Fludarabine (150mg/m^2)+ Alemtuzumab (54mg/ m^2) (n = 11). Median time to neutrophil and platelet recovery was 14.5 (8–38) and 32.5 (10–99) days, respectively. Median number of platelet and PRBC tranfusions was 6(0–32) and 3(0–11), respectively. The incidence of aGVHD (Gr II-IV) was 33%. One patient had primary graft failure and the incidence of VOD was zero. Median drop in estimated CrCL from pre transplant to 30 days post was 40% (0–68). The median highest grade of mucositis was 1 (0–3) with median number of days on TPN 0 (0–38) and median number of days requiring a PCA 0 (0–30). The median number of days with fever 3 (0–21) and the median number of infections per patient 1 (0–2) of which 2 patients required line removal. Three patients required ICU transfer. Day 100 NRM was 2%.

Conclusions: RIC-AlloSCT is safe, well tolerated, and associated with significantly lower NRM. We hypothesize RIC will demonstrate a decrease in nursing time and complexity of care. Therefore, we are in the process of collecting data on our patients who had a myeloablative AlloSCT to compare the incidence of various toxicities and subsequent nursing supportive care needs to our RIC-AlloSCT experience.

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EASING THE TBI EXPERIENCE IN THE PRE-SCHOOL PATIENT

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Pediatric patients in the pre-school age group can pose unique challenges for their care team and caregivers when undergoing preparative therapy for transplantation. This is especially true when total body irradiation (TBI) is included in the preparative regimen. Typically, TBI in the pre-school patient involves the use of general anesthesia (GA) to ensure proper positioning, cooperation, and general patient safety. TBI treatments at our center are given outpatient in BID fractions, over 4–5 days. A consult with anesthesia is included in the pre-transplant work-up, and the caregiver is given detailed information about keeping the child NPO for 4–6 hours, not only once, but twice daily. As a result, many of these children need daily IV fluids in our clinic. To address these challenges, our center implemented a program designed to identify preschoolers as potential candidates to receive their TBI treatments without GA. Initial discussions between the transplant nurse coordinator and the caregiver provide education regarding TBI. The patient is then scheduled for a consultation with the pediatric radiation oncologist. Discussion includes the option for the patient to have a "practice" TBI session. We have found this session key in identifying children who could receive TBI without GA. The practice session involves collaboration of skilled radiation therapy technicians and Child Life Specialists. Age appropriate techniques are used to help the patient practice their treatment position. The child is taught how and why the legs and forehead may be taped to help hold them steady. Children have the choice of watching a favorite video, or talking to their caregiver through in intercom system. The treatment door is closed for 5–7 minutes, simulating an actual treatment. If the session is successful, the