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PROGRAM OVERVIEW: DISEASES TREATED, TYPES OF TRANSPLANTS, REGIMENS AND OUTCOMES IN AN OUTPATIENT BLOOD AND MARROW TRANSPLANT PROGRAM

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The Blood and Marrow Transplant program at US Oncology at Baylor University Medical Center in Dallas, TX expanded its outpatient facility in May 2002 to a 14, 000 square foot facility with 16 infusion chairs, 6 private rooms and 15 exam rooms. The outpatient clinic is open 7 days a week, from 8 AM until 7PM. There are 5 attending physicians, 10 infusion nurses, 5 transplant coordinators, 1 pharmacist, pharmacy technicians and numerous administrative support personnel. The outpatient clinic has its own pharmacy infusion satellite and offers laboratory services. In 2001, we performed 168 total transplants with 26 (15%) of those being initiated on an outpatient basis. In 2002, year to date, we have performed a total of 109 transplants, with 25 (23%) of patients being done primarily on an outpatient basis. Of the 25 patients treated in 2002, the diseases include AML (2), MDS (1), CML (1), Hodgkin's Disease (2), Multiple Myeloma (4), NHL (13), Ovarian (1) and Waldenstrom's Macroglobulinemia (1). There were 17 autologous transplants, 3 allogeneic sibling transplants, and 5 matched-unrelated donor transplants done on an outpatient basis. The preparative regimens used in the outpatient transplants include BEAM (8), Melphalan (5), ThioTepa/TBI (2), BUS/CTX (2), Carbo/TT (1), and CTX/TBI (1). Six patients received non-ablative transplants using Flud/TBI (5) and Flud/CTX (1). Of the 25 outpatients treated, 12 (48%) had to be admitted within the first 30 days of transplant for a median of 3 days. The primary reasons for admission include mucositis, nausea/vomiting and febrile neutropenia. There were 23 of 25 patients (92%) alive at Day 90 post transplant. Of the patients treated in 2002, there have been 2 deaths, 1 due to complications of recurrent AML, and 1 due to graft-versus-host-disease. When appropriate resources are available, outpatient transplants can be safe and effective in selected patients.

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PROGNOSTIC FACTORS FOR DAY 100 TRANSPLANT RELATED MORTALITY (DAY 100 TRM) FOLLOWING HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT): A RETROSPECTIVE ANALYSIS OF 459 PATIENTS TRANSPLANTED AT A SINGLE INSTITUTION

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Objective: To determine predictive factors for non-relapse mortality before day100 (day 100-TRM) following HSCT. **Patients:** Consecutive 459 patients (pts) who received HSCT at Tokyo Metropolitan Komagome Hospital between January 1990 and December 2001. Median age was 43 yrs (range, 0-67) and 277 were male. Among them, 354 were allograft recipients (211 from related, 139 from unrelated and 4 from syngeneic donor) and remaining 105 received autologous HSCT. The preparative regimens were 12Gy of TBI based (130pts), busulfan based (227pts) or others (102pts). **Results:** Day-100 TRM occurred in 40 pts and Kaplan Meier estimate of the incidence was 9.0%. In univariate analysis, day-100 TRM occurred more frequently among pts with allograft than autograft (10.7% vs 3.1%, Logrank P = 0.024). Among pretransplant variables, serum ALT greater than 50 IU/L (21.8% vs 6.1%, P < 0.0001) was the most significant factor predicting day-100 TRM though Age older than 44 (12.1% vs 8.0%, P = 0.16), TBI containing regimen (9.5% vs 8.9%, P = 0.81), vital capacity less than predicted (12.9% vs 9.6%, P = 0.34), FEV1.0 less than 80% of total expiratory volume (9.7% vs 8.9%, P = 0.93) or ejection fraction less than 60% (12.4% vs 11.6%, P = 0.80) were not significantly associated with day 100 TRM. In Cox regression model, allograft and serum ALT were independent predictors adjusted for other factors. **Conclusion:** High serum ALT before transplant may be highly predictive of early toxic death after HSCT. At our institution, Bu/Cy regimen was used frequently and may be related to these results.

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VALACYCLOVIR COMPARED TO ACYCLOVIR FOR CYTOMEGALOVIRUS PROPHYLAXIS IN ALLOGENEIC STEM CELL TRANSPLANTS RECIPIENTS

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Conditioning regimens using alemtuzumab (Campath -1H) are associated with rates of cytomegalovirus (CMV) infection as high as 85-100% in seropositive donor/recipient pairs. High dose acyclovir reduces the incidence of CMV viremia. A recent randomized study demonstrated a further reduction in CMV viremia with the use of high dose oral valacyclovir after myeloablative transplantation(Ljungman Blood 2002). We analyzed CMV positive donor and/or recipient subjects who underwent an allogeneic SCT protocol conditioned with fludarabine 30 mg/m2/d (D-7 to D-3), alemtuzumab 20 mg/d (D-7 to D-3), and melphalan 140 mg/m2 (D-2). All patients initially received acyclovir prophylaxis. CMV infection was defined as any positive CMV test by polymerase chain reaction (PCR), antigen test, or culture. Early (during hospitalization) CMV infection was identified in 6/26 subjects at a median of 20 days despite acyclovir prophylaxis. Upon discharge, the initial nine patients received oral acyclovir (usually 800mg po qid). After a policy change, the subsequent 11 patients received valacyclovir (2 gr po qid). Of the patients who did not reactivate in the hospital, 6/9 on oral acyclovir and 3/11 on valacylovir developed infection, respectively (p= 0.07). One patient with CMV viremia and adenovirus in the urine died on day 121 with an interstitial pulmonary infiltrate. At autopsy, occasional alveolar cells were positive for CMV. In summary, oral valacyclovir tended to be more effective than acyclovir at reducing reactivation after hospital discharge. These data further confirm the high incidence of CMV reactivation with alemtuzumab based conditioning regimens despite aggressive prophylaxis. Alternative regimens to reduce early CMV reactivation are needed.

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ALTERNATE DAY GANCICLOVIR/FOSCARNET (GAN/FOS) FOR CYTOMEGALOVIRUS PROPHYLAXIS IN AT RISK ALLOGENEIC STEM CELL TRANSPLANT RELATED AND UNRELATED RECIPIENTS IS 100% EFFECTIVE IN PREVENTING CMV INFECTIONS

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The incidence of cytomegalovirus (CMV) infection post AlloSCT has been reduced by prophylactic Gan (56% to 20%) (Winston DJ et al, Ann Intern Med 1993; 118:179), but has been associated with significant hematopoietic toxicity and secondary graft failures. An alternative effective agent against CMV is Fos (Oberg B et al, Pharmacol Ther 1989; 40:1213), but is associated with nephrotoxicity and electrolyte imbalances. Since both Gan and Fos are effective against CMV but have different toxicity profiles, we evaluated the efficacy and safety of alternate day Gan/Fos for CMV prophylaxis. AlloSCT pts (n=9) that were serologically CMV (-) donor/(-) recipient received leukodepleted blood products (LDBP). 16 pts who were CMV (+) and/or had a CMV (+) donor received prophylaxis with IV Fos at 90 mg/kg Q48H alternating with IV Gan at 5 mg/kg Q48H, initiated at ANC $\geq$750/mm^3 until Day +100. M:F 9:7; age 9.5 $\pm$ 6.6 (0.8-18 yr); 1 APL CR2, 1 Wilms' SD, 1 Hurler's SD, 2 CML CP, 1 AML CR2, 1 SAA, 2 ALL CR2, 2 Beta-Thal, 1 ALL CR3, 1 HD PR2, 1 HD CR2, 1 ALCL PR, 1 NBL PD; Donors: 5 RPBSC 6/6, 1 RPBSC 5/6, 3 RBM 6/6, 2 UCB 5/6, 5 UCB 4/6. GVHD prophylaxis: Tacro/MMF. TNC and CD34 for BM/PBSC was 6.6 $\pm$ 6.1 x10^8/kg and 5.2 $\pm$ 3.1 x 10^6/kg, and UCB $\pm$ SD were 4.9 $\pm$ 5.4 x10^7/kg and 2.4 $\pm$ 1.6 x 10^5/kg, respectively. Despite an incidence