The median dose for patients receiving BM (2.7×10^8/Kg) gave the greatest discrimination.

In multivariate analyses, high dose BM compared to PB, was associated with lower TRM (RR = 0.61 ; 95% CI 0.39-0.98; p = 0.04), better Leukemia Free Survival (RR = 0.65; 95% CI 0.46-0.91; p = 0.013), and better Overall Survival (RR = 0.64 ; 95% CI 0.44-0.92; p = 0.016). **Conclusion:** The present study in patients with AML allografted in first remission, indicates a better outcome with marrow as compared to PB, when the dose of marrow infused is rich.

10

LONG-TERM FOLLOW UP AFTER NON-MYELOABLATIVE ALLOGENEIC STEM CELL TRANSPLANTATION FOR RENAL CELL CARCINOMA: THE UNIVERSITY OF CHICAGO EXPERIENCE

Artz, A.S.[1], van Besien, K.[1], Zimmerman, T.[1], Gajewski, T.F.[1], Rini, B.[2], Hu, S.[3], Stadler, W.M.[1], Vogelzang, N.J.[1] 1. University of Chicago Hospitals, Chicago, IL; 2. The University of California San Francisco, San Francisco, CA; 3. St. John Mercy Medical Center, St. Louis, MO

Non-myeloablative hematopoietic allogeneic stem cell transplant (NST) for metastatic renal cell carcinoma (RCC) has been demonstrated to induce remissions in select patients (pts). However, there are no long-term data on response duration, progression after response, or overall survival. We report the long-term follow up of NST for cytokine refractory metastatic RCC at the University of Chicago treated on a single protocol. Between 2/99 and 5/03, 18 pts underwent 19 matched-sibling peripheral harvested NST's after conditioning with fludarabine and cyclophosphamide. Post-transplant immunosuppression was with mycophenolate mofetil until day 60 and tacrolimus tapering at day 90. Median age was 55 years, performance status (PS) was 1 in 6/19 pts (PS = 0 in the remainder), and hemoglobin (Hb) < 12 g/dL in 8/19 (42%). There were 4 partial responses, but all have since progressed with a median response duration of 609 days (range, 107-926). All responders had chronic GVHD and were on immunosuppression when progressive disease (PD) occurred. In 3 of 4 responders, PD occurred at a site of prior response. Among all pts, DLI and/or interferon were given to 3 pts for PD without response. Six pts died early (ED) before day 120. Transplant related mortality was 4/6 among those with ED and 5/18 (28%) overall. Among those without ED or response, 7/9 died from PD. All responders are alive at a median of 1035 days (range 900-1405). The combination of anemia and decreased PS was associated with adverse transplant outcome ($P = .035$) and reduced survival ($P = .004$). Responders had prolonged survival ($P = .002$) compared to non-responders. In conclusion, NST for RCC as performed here leads to long term but not durable partial responses and is associated with prolonged survival in a minority of pts. Risk stratification with simple clinical factors such as anemia and PS > 0 may reduce acute mortality and enrich the population for potential responders, but further improvements in adoptive immunotherapy are necessary before NST can be more generally applied for RCC.

Table. *Influence of Patient Factors on NST for RCC*

Factor	Partial Response (%) N = 4	Other (%) N = 9	Early Death (%) N = 6	Across Groups *P* value N = 19	Survival *P* value N = 18
Pretreatment					
PD at transplant	2 (50)	5 (83)	5 (56)	0.57	.37
Hb < 12 g/dL	1 (25)	3 (33)	4 (67)	.48	.06
PS > 0	0	2 (22)	4 (67)	.06	<.01
Hb < 12 g/dL and/or PS > 0	1 (25)	4 (44)	6 (100)	.04	<.01
GVHD					
aGVHD > 1	0	1 (11)	2/5 (40)	.23	.03
cGVHD, ext	4 (100)	3 (33)	n/a		.76

Nineteen transplants performed with 18 patients. "Other" includes patients who did not respond or suffer early death. Across group comparison uses a two-tailed Fisher's exact test for a 3 × 2 table. Survival analysis is for 18 patients. *P* value derived from univariate log-rank test for each variable.

11

ALLOGENEIC TRANSPLANTATION FOR MANTLE CELL LYMPHOMA

Bence-Bruckler, I.A.[1], Bierman, P.J.[5], Bociek, G.R.[5], Stewart, D.A.[3], Gingrich, R.[2], Vose, J.M.[5], Bredeson, C.N.[4], Rosenblum, M.[4], Lynch, J.C.[3], Armitage, J.O.[5] 1. University of Ottawa, Ottawa, ON, Canada; 2. University of Iowa, Iowa City, IA; 3. University of Calgary, Calgary, AB, Canada; 4. Medical College of Wisconsin, Milwaukee, WI; 5. University of Nebraska Medical Center, Omaha, NE

The prognosis of mantle cell lymphoma (MCL) is poor with a median survival of generally less than three years. In an attempt to improve on the outcome of this disease, high dose therapy in the form of both autologous and allogeneic stem cell transplantation (SCT) has been explored. However, recurrences following autologous transplantation are common. Allogeneic SCT offers the potential benefits of an uncontaminated stem cells and a graft versus lymphoma effect.

Thirty-seven patients with MCL underwent allogeneic SCT at five institutions between 1994 and 2003. The median age at transplant was 48 (range 34-59) years; 6 patients were female and 31 male. The median interval from diagnosis to transplant was 11 months (range 4-144 months). Seventy percent of patients had received at least two prior chemotherapeutic regimens and 9% had failed an autologous SCT. Donor source was matched related donor (MRD) in 33 (89%) and matched unrelated donor (MUD) in 4 (11%). Conditioning regimens varied by center; overall 26 patients (70%) received TBI-based conditioning. Donor source was bone marrow in 14 (38%) and peripheral blood in 23 (62%). Fourteen grafts (38%) were T-cell depleted and of these, 7 received T-cell add-back. With a median follow-up for surviving patients of 42 months (range 4-98 months), sixteen patients remain alive post SCT. The cumulative incidence of non-relapse mortality is 32% at day 100 and 41% at one year post transplant, with the vast majority of deaths occurring by one year post transplant. Thirty four of 37 patients were evaluable for acute graft-versus-host disease (GVHD). The cumulative incidence of acute GVHD was 62% at 100 days. Of 20 patients evaluable for extensive chronic GVHD, the cumulative incidence was 30% at one year. Three year estimates of event-free and overall survival are 39% (95% CI 23%-55%) and 45% (95% CI 28%-61%) respectively. Progressive disease has been documented in six patients. This data demonstrates that allogeneic SCT in MCL can result in prolonged disease control in selected, pretreated patients, although nonrelapse mortality remains a significant problem with this approach.

12

DISSECTION OF AN MHC MISMATCHED ALLOGENEIC TRANSPLANT MODEL DURING DONOR $CD4^+CD25^+$ T-CELL FACILITATION OF HEMATOPOIETIC PROGENITORS

Hanash, A.M., Levy, R.B. University of Miami School of Medicine, Miami, FL

Identifying cell populations capable of supporting allogeneic hematopoietic stem/progenitor cell engraftment without inducing GVHD could lead to more potential hematopoietic cell transplant (HCT) recipients and broaden the acceptable donor pool. We have examined the effect of $CD4^+CD25^+$ regulatory (T-reg) cells on engraftment in a sublethal (7.0 Gy TBI) MHC mismatched model by transplanting donor C57BL/6 (B6) T-regs and T-cell depleted bone marrow (BM-TCD) into BALB/c recipients and observed long-term chimerism ($p < .05$) and diminished rejection ($p < .05$). This non-GVHD inducing T-cell population was also associated with significantly greater splenic lineage committed (GM, $p < .001$) and multi-potential (HPP, $p < .05$) donor progenitor colonies 7 days post-BMT. To dissect the allogeneic transplant components involved in this progenitor support, splenic day 7 donor GM progenitors were assessed following transplants eliminating donor T-regs' allo-recognition in the recipient and transplants selectively neutralizing populations in the recipient capable of allogeneic rejection. T-regs from BALB/c × B6 F1 mice significantly increased donor B6 colonies whether transplanted into recipients lacking (BALB/c, $H\text{-}2^d$, $p < .001$) or possessing (BALB.K, $H\text{-}2^k$, $p < .05$) MHC that was allogeneic to the donor T-regs. Importantly, when eliminating the recipients' T-cell resistance by