Poster Session I

(SLE) (8%). Twenty-seven patients received allogeneic HCT (alloHCT) for SSC (n=7), amyotrophic lateral sclerosis (n=6), autoimmune cytopenias (n=6), SLE (n=2), autoimmune enteropathy (n=1) and unclassified AI (n=3). The median age at HCT did not differ by transplant type (41 vs. 36 years for autoHCT and allo-HCT, respectively) and most patients (66%) had a good performance score at HCT. The median time from diagnosis to transplant was 58 and 34 months for autoHCT and alloHCT, respectively. Irradiation-containing conditioning regimens were used in 109 cases (61%) and cyclophosphamide either alone or in combination with other agents without irradiation in 45 cases (25%). Most autoHCT recipients received total body irradiation, cyclophosphamide and anti-thymocyte globulin (64%). Peripheral stem cell cells were the predominant graft type; and 56% of these grafts were manipulated ex vivo (CD34+ cell selection or T-cell depletion). The probabilities of 100-day mortality were 10% (95% confidence interval [CI], 6-15%) and 17% (95% CI, 5-35%) after autoHCT and alloHCT, respectively. Corresponding one-year probabilities of overall survival were 89% (95% CI, 83-93%) and 75% (95% CI, 54-91%). One-year probability of overall survival post-autoHCT were 96%, 82% and 73% for MS, SSC and SLE respectively. In summary, these collective data from CIBMTR, MS and SSC are the most common autoimmune disease indications for HCT.

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AUTOLOGOUS HEMATOPOIETIC STEM CELL TRANSPLANTATION (AH-SCT) FOR EARLY ONSET TYPE I DIABETES MELLITUS

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Introduction: Type I Diabetes mellitus (DM1) is an autoimmune disease that destroys pancreatic islet cells were insulin is producted, leading to insulin dependence and chronic complications such as retinopathy, nephropathy, neuropathy and coronary atherosclerosis.

Objectives: Evaluate the efficacy and toxicity (phases I/II) of high-dose cyclophosphamide (Cy) and rabbit anti-thymic globulin (rATG) followed by rescue with AHSCT in patients with less than 6 weeks from diagnosis of type 1 Diabetes mellitus.

Materials and Methods: Stem cells were mobilized from the bone marrow with Cy $(2g/m^2)$ and Filgrastim $(10\mu g/kg/d SC)$, collected by leukapheresis and cryopreserved. Patients were conditioned with Cy $(50mg/kg \ x \ 4)$ and rATG (4.5 mg/kg), followed by stem cell infusion.

Results: Since December 2003, 15 patients were enrolled in this study. The medium age was 19.2 years, (14-31 years), and the time between diagnosis and mobilization was 34.7 days (24 to 49 days). The mean hospitalization period was 24,2 days (16-57 days) and the average number of CD34+ infused cells was 10.8×106/kg (5.8-23.19×106/kg). Neutrophil engrafted on days 8 to 10 (average of 9,3 days) and platelets engrafted on days 0 to 15 days (average 12.3 days). There were no deaths. Most patients had neutropenic fever, but only one developed serious complications needing intensive care due to bilateral pneumonia, reversed with antibiotic therapy and non-invasive ventilation. All patients were using exogenous insulin therapy before mobilization, with an average dose of 0.38 Ul/kg (0.13 to 0.58 Ul/kg). In a mean follow-up of 14.2 months (1- 31 months), insulin therapy was suspended in 12 patients from D-7 to D+39 (average +32), two patients decreased insulin dose (16 and 21% compared to the period before AHSCT) and one patient remains using high dose insulin (1.7 Ul/kg/d). This last patient was the only one that presented ketoacidosis pre-AHSCT and received corticosteroids in the pre-conditioning period. Six to twelve months after AHSCT, the peptide-C levels considerably increased in 7 patients with clinical response and glycated hemoglobin values are <7%.

Conclusion: These results indicate that high-dose immunosuppression associated with AHSCT may induce prolonged clinical remission of Type 1 diabetes mellitus, without significant toxicity. The durability of response will be evaluated in longer follow-up.

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SERIAL SKIN BIOPSIES DEMONSTRATE REDUCED DERMAL FIBROSIS AFTER AUTOLOGOUS HEMOPOIETIC STEM CELL TRANSPLANT (A-HSCT) FOR SEVERE SYSTEMIC SCLEROSIS (SSS)

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Background: In a multiinstitutional study, 34 patients with SSS received high-dose immunosuppressive therapy followed by A-HSCT. Serial evaluations included improvement in the modified Rodnan skin score (mRSS, 51-0) and histologic dermal fibrosis score (DFS), grades 0-5.

Methods: 10 patients had 23 pre and post HSCT serial biopsies, mean follow-up 4 years. Punch biopsies from each patient were obtained from the same location on the lateral upper or lower arm. The DFS was based on the depth and % of dermal homogenization, size orientation and eosinophilia of fibers, and interstitial space between the fascicles in H&E -stained sections. The mRSS showed a significant improvement in 8/10 patients. The mean decrease in mRSS of 34 patients' (baseline 30.2) to final evaluation was 22.08 (-70.3%, and with a significant linear decrease over time, both $p = \langle 0.0001 \rangle$. The DFS in 7 of 10 had ≥ 3 grades of reduction. 3 had a final DFS of 0 with reduction of dermal thickness, loss of homogenization thinning and straightening of the collagen bundles with an increase in interstitial space. The dermalepidermal border remained straightened with loss of rete ridges and loss of elastica in the papillary dermis. The discordant final scores in patient 8, decrease in DFS without decrease in mRSS was likely related to localized improvement of skin at site of biopsy.

Conclusion:

A-HSCT for SSS leads to remodeling of dermal collagen with loss of sclerosis and corresponding improvements in the mRSS.

RESULTS: Assessment of dermal fibrosis after A-HSCT for SSS

Patient	Baseline mRSS/DFS	Final Score Year/mRss/DFS
	Integrate	
I	35/3	2/3/1
2	16/3	6/0/0
3	40/5	5/10/0
4	26/4	1/18/3
5	19/4	5/1/1
6	20/5	4/7/3
7	30/4	4/8/0
8	48/5	4/42/1*
9	44/5	4/10/1
10	29/5	3/12/2

AUTOLOGOUS TRANSPLANTS

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PREVENTION OF MUCOSITIS IN AUTO BMT/STEM CELL TRANSPLANT PATIENTS

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It is estimated that 80% of patients who undergo high-dose chemotherapy plus or minus radiotherapy prior to transplantation develop mucositis. Mucositis is a painful complication, which can lead to poor nutrition, increased use of narcotics, dehydration, greater risk for infection and bacteremia, as well as altered quality of life. Patients can have oral ulceration, epigastric discomfort, diarrhea, rectal irritation, and bleeding. It is likely that the complications of mucositis can contribute to increased lenght of stay during stem cell transplantation.

The purpose of this study is to compare patients who received Kepivance(palifermin) as part of their treatment with patients that did not receive this medication during autologous stem cell trans-