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Title: Nutrition-related outcomes for autologous stem cell transplant patients

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ABSTRACT

Microabstract: Autologous stem cell transplant patients are at risk for malnutrition, which may be linked to negative clinical outcomes. A retrospective, observational study examined data related to 330 consecutively admitted adults. Patients at high malnutrition risk had longer hospital stays, increased nosocomial infections, and increased one-year mortality. Further studies are needed to investigate whether early nutrition intervention could improve these outcomes.

Introduction: Autologous stem cell transplant patients are at risk for malnutrition prior to transplant admission as well as malnutrition acquired during their transplant admission.

Patients and Methods: A retrospective, observational study examined data related to consecutive adults (n = 330) admitted for ASCT between 2014 and 2016 at the Hospital of the University of Pennsylvania. Malnutrition risk on admission (identified by the Malnutrition Screening Tool) and transplant-associated weight loss were analyzed for independent associations with hospital length of stay, nosocomial infection, intensive care unit transfer, deconditioning, time to platelet and neutrophil engraftment, 30-day readmission, and one-year mortality.

Results: Adults with high malnutrition risk (n = 60) had a longer median hospital stay ($p = 0.004$), longer median time to platelet engraftment ($p = 0.022$), increased nosocomial infections ($p = 0.047$), and increased one-year mortality ($p = 0.036$). Adults with high transplant-associated weight loss (n = 100) experienced longer hospital stays ($p < 0.001$) and more ICU transfers ($p = 0.001$). Outcomes for deconditioning, time to neutrophil engraftment, and 30-day readmission did not differ significantly based on nutrition risk or weight loss.

Conclusion: Further research is needed to determine whether early nutrition intervention would improve these outcomes.

INTRODUCTION

High dose chemotherapy followed by autologous stem cell transplantation (ASCT) is typically offered to patients with advanced hematologic malignancies who have previously suffered from disease- and therapy-related complications that may result in deterioration of nutrition status and malnutrition. Muscle loss prior to ASCT has been linked to increased rates of complications and longer hospital stays[1].

Additionally, ASCT bears a risk of acute malnutrition due to its association with gastrointestinal toxicities[2]. A typical hospital stay for ASCT is two to three weeks, during which patients may experience inadequate oral intake and associated weight loss. Weight loss and deterioration of nutrition status have been observed in ASCT patients[3,4,5], but questions remain as to whether these changes are associated with negative clinical outcomes.

The purpose of this study was to determine whether malnutrition risk at admission or weight loss during admission for ASCT was linked to important clinical outcomes.

PATIENTS AND METHODS

A retrospective analysis of existing data from patient medical records was approved as a quality improvement project by the Institutional Review Board of the University of Pennsylvania. All consecutive adult patients admitted for ASCT between July 1, 2014 and June 30, 2016 (n = 346) were included. Patients with privacy restrictions on retrospective access of their electronic medical records (n = 9) were excluded, as were patients who were part of a clinical trial involving a planned extension of hospital stay (n = 7), for a final sample of 330 patients. Demographic and clinical information included age, sex, BMI, Karnofsky Performance Status (KPS), diagnosis, time from diagnosis, number of previous lines of therapy, and whether it was a patient's first or a subsequent ASCT.

Malnutrition risk on admission was interpreted as a dichotomous variable determined using the validated Malnutrition Screening Tool (MST), where a score ≥ 2 out of a maximum of 7

indicates high risk of malnutrition, and 0 or 1 indicates low risk. This tool, administered by the nurse at admission, elicits whether patients have experienced recent unintended weight loss, and if so, how much. Nurses administering the MST also ask patients if they are experiencing decreased oral intake related to poor appetite[6]. See Figure 1. The MST is simple to administer and to embed in the electronic medical record, making it a feasible measure of malnutrition risk.

Transplant-associated weight loss was considered a surrogate for deterioration of nutrition status during admission. This value was obtained by subtracting the weight documented at first outpatient visit post-discharge (typically within six to ten days) from the patient's recorded weight on admission to the hospital. Based on Baumgartner's findings that >7% weight loss during allogeneic stem cell transplant was associated with increased hospital length of stay[7], a dichotomous variable of high/low weight loss was created with a threshold of 7%.

Clinical outcomes were reported both during the hospital stay and after discharge. To control for varied time of conditioning regimens, length of hospital stay was reported as time to discharge alive, measured from the day of stem cell infusion to the day of discharge. Other outcomes during hospitalization were culture-positive infections, transfer to the intensive care unit (ICU), time to neutrophil engraftment >0.5 thousand/μL, time to platelet engraftment >20 thousand/μL, and deconditioning on discharge (as defined by referral to home physical therapy services or placement at a rehabilitation or skilled nursing facility). Hospital readmissions within 30 days of the ASCT admission and one-year mortality or referral to hospice were also included.

Statistical Methods

Continuous variables were reported as median (interquartile ratio) and categorical variables as frequency (percentage). Analyses were performed using SPSS 25.0 (IBM Corporation, Armonk, NY). $P < 0.05$ was considered statistically significant.

Mann-Whitney U tests were conducted to compare median hospital length of stay between adults with high vs. low malnutrition risk, and with high vs. low weight loss. Further Mann-Whitney U tests compared median time to neutrophil and platelet engraftment with high vs. low malnutrition risk, and with high vs. low weight loss.

Binary logistic regressions with high/low malnutrition risk and high/low weight loss as independent variables were performed for dichotomous outcomes (culture-positive infection, transfer to the ICU, deconditioning on discharge, 30-day hospital readmission, and one-year mortality/hospice referral). Regression models were adjusted for age, sex, KPS, conditioning regimen, and repeat ASCT, which were evaluated for multicollinearity. A sensitivity analysis was conducted using the same approach but with exclusion of patients transferred to the ICU as a strategy to evaluate the impact of ICU transfer on these outcomes.

RESULTS

Patient characteristics are reported in Table 1. The sample included 192 men and 138 women. Median age was 59 years and median BMI was 28 kg/m^2. High malnutrition risk was identified in 60 patients (18%). See Figure 2 for distribution of scores.

Plasma cell disorders were the most common diagnosis group, with these patients receiving high-dose melphalan as their conditioning regimen. Hodgkin and non-Hodgkin lymphoma was the second most common diagnosis group, and patients received carmustine, cyclophosphamide, and etoposide (BCV) or carmustine, etoposide, cytarabine, and melphalan (BEAM) for their conditioning regimen. Other diagnoses included germ cell tumors and acute myelogenous leukemia (AML), with these patients receiving carboplatin/etoposide or busulfan/cyclophosphamide. Median time from diagnosis was 0.8 years, and the median number of previous lines of therapy was two. Twenty-six patients (8%) had undergone ASCT in the past.

The median transplant-associated weight loss was 4.4 kg (5.4%) and 30% of patients experienced high (>7%) transplant-associated weight loss. Patients with high malnutrition risk on admission were older, had lower median BMI, and lower median KPS. They were also more likely to have undergone a previous ASCT. Only 16 patients (5%) who presented with high malnutrition risk also experienced high weight loss. One hundred forty-four patients (44%) had either high malnutrition risk on admission or experienced high transplant-associated weight loss.

Malnutrition Risk on Admission

Risk of malnutrition was associated with negative clinical outcomes (Table 2). For patients with high malnutrition risk, median [IQR] length of stay (15 [13-18] versus 13 [12-16] days, p = 0.004) and time to platelet engraftment (20 [18-24] versus 19 [17-21], p = 0.022) were longer. Those at high risk of malnutrition were more likely to experience a culture-positive infection during the transplant admission (univariate OR = 2.39, 95% CI: 1.34 – 4.25, p = 0.003; multivariate OR = 1.91, 95% CI: 1.01 - 3.63, p = 0.047) and to die or be referred to hospice within one year of discharge (univariate OR = 2.49, 95% CI: 1.19 – 5.19, p = 0.015; multivariate OR = 2.66, 95% CI: 1.07 – 6.60, p = 0.036). Adults at high risk of malnutrition were more likely to be deconditioned at discharge compared to adults at low risk of malnutrition on a univariate analysis, but this relationship was not significant in a multivariate analysis (univariate OR = 2.66, 95% CI: 1.43 – 4.97, p = 0.002; multivariate OR = 1.92, 95% CI: 0.92 – 4.00, p = 0.082). Malnutrition risk was not significantly associated with time to neutrophil engraftment, ICU transfer, or 30-day hospital readmission.

Transplant-Associated Weight Loss

Weight loss during the hospital admission was associated with negative clinical outcomes (Table 3). Patients with high weight loss had longer median [IQR] length of stay (15 [13-19] versus 13 [12-15], p < 0.001) and greater odds of transfer to the ICU (univariate OR =

4.38, 95% CI: 1.77 – 10.80, p = 0.001; multivariate OR = 6.09, 95% CI: 2.19 – 16.89, p = 0.001) than adults with low weight loss. The majority of ICU transfers (80%) were attributable to severe sepsis. We performed a sensitivity analysis to determine whether ICU stays were driving the association between high weight loss and longer length of stay. After excluding the twenty-six patients who were transferred to the ICU, patients with high weight loss continued to have longer median length of stay (14 [13-17] versus 13 [12-13], p < 0.001). High transplant-associated weight loss was not significantly associated with time to neutrophil or platelet engraftment, culture-positive infection, deconditioning at discharge, 30-day hospital readmission, or one-year mortality.

DISCUSSION

Although a minority of patients admitted for ASCT at our center had high risk of malnutrition identified by their MST score, they experienced longer hospital stays, longer time to platelet engraftment, more infections, and increased one-year mortality. Patients with significant weight loss during the hospital admission experienced more ICU transfers and longer hospital stays. These combined findings suggest that ASCT patients may benefit from nutritional interventions prior to and/or during ASCT admission in order to prevent adverse clinical outcomes.

Our findings of negative outcomes associated with malnutrition risk on admission are consistent with others. In 56 allogeneic SCT patients, Thomaz et al. observed that decreased arm muscle area (indicative of low muscle mass) was associated with 180-day mortality[8], similar to our finding of increased one-year mortality in patients at high risk for malnutrition. In a study by Horsley et al. evaluating seven allogeneic SCT and 59 ASCT patients, mean length of stay was higher in patients identified with malnutrition by the Patient-Generated Subjective Global Assessment, similar to our results[9].

Deterioration in nutrition status has been described by others. Barritta de Defranchi et al. in a mixed group of 99 ASCT and 24 allogeneic stem cell transplant patients confirmed that patients with a greater deterioration in patient-generated subjective global assessment scores had an increased hospital length of stay[4]. In 20 ASCT patients, most of whom were well-nourished prior to admission, Hung et al. noted significant decreases in weight, lean body mass, nutrition status, and physical activity level as measured by the Patient-Generated Subjective Global Assessment[3]. These studies agree with our findings that nutrition status deteriorated throughout admission, but our study adds linkages to additional negative clinical outcomes.

Nutrition practices vary widely based on institution, as has been noted previously[12]. Nutrition practices at our center for ASCT patients have historically been based on the discretion of the supervising physician. Median hospital day of the first assessment by a Registered Dietitian was hospital day #9 during this study period. Enteral or parenteral nutrition was provided to 25 (7%) of patients. Given that 48% of patients were at high malnutrition risk on admission or experienced >7% weight loss during transplant, earlier and more aggressive nutrition intervention may have helped to improve outcomes.

Guidelines issued by the American Society of Parenteral and Enteral Nutrition recommend universal nutrition screening for all ASCT patients and consideration of enteral or parenteral nutrition for patients who are malnourished and are likely to continue with inadequate oral intake for a prolonged period of time[2]. Further research is needed to determine whether such an approach tailored to malnutrition status could improve the clinical outcomes evaluated in this study. Due to the significant number of patients who were at low malnutrition risk on admission but went on to experience high weight loss, universal nutrition screening on admission may be insufficient. It may be more beneficial for all ASCT patients to be followed by a Registered Dietitian throughout their admission regardless of malnutrition status on admission.

Our study has both strengths and limitations. First, our review has a larger sample size than several similar studies[1,3,4,7,8,9,10,11]. It has the advantages of consecutive enrollments and a

narrow focus on autologous transplant patients. Second, our innovative use of the MST as a screening tool has the advantage of potential ease of adoption at other centers. Third, it correlates malnutrition risk and transplant-associated weight loss to meaningful clinical outcomes in this population.

Limitations of the study include its single-center, retrospective design. Thus it may not be representative of the patient populations or therapeutic options at other sites. Transplant-associated weight loss was not a baseline characteristic present at time of admission; therefore its association with increased length of stay and increased risk of ICU transfer are merely descriptive of the course of admission. Our retrospectively-collected study data did not include objective measurements of body composition or formal malnutrition assessments. Additionally, we cannot easily account for the impact of concurrent changes in clinical practice that may have affected patient outcomes, such as the implementation of levofloxacin prophylaxis in the final six months of the study period.

Both high malnutrition risk on admission for ASCT and high weight loss during the hospital admission were linked to negative clinical outcomes in this large retrospective sample. Prospective studies of nutritional intervention prior to and/or during ASCT admission are warranted to assess the potential impact of nutritional therapy on these outcomes.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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Clinical Practice Summary

Hematopoietic stem cell transplant patients are known to be at risk for malnutrition. Malnutrition and transplant-associated weight loss have previously been linked to increased length of stay and increased mortality, primarily in studies that examine allogeneic stem cell transplant patients or mixed groups of allogeneic and autologous stem cell transplant patients. This study confirms these findings in a group of a larger sample size which is solely focused on autologous stem cell transplant patients, and demonstrates associations between nutrition status and additional clinical outcomes. It identifies the validated Malnutrition Screening Tool as a useful predictor of negative clinical outcomes,

which may allow for identification of patients who are in particular need of early nutrition assessment.

Table 1: Patient Characteristics

	Median (IQR) or n (%)			
	All patients (n = 330)	**Low Malnutrition Risk (n = 261)**	**High Malnutrition Risk (n = 60)**	**p-value**
Age (years)	59 (52 - 65)	58 (52 - 64)	61 (54 - 68)	0.044*
Sex				
Male	192 (58)	160 (61)	31 (52)	0.170
Female	138 (42)	101 (39)	29 (48)	
BMI (kg/m^2)	28 (25 - 32)	28 (25 - 32)	26 (24 - 30)	0.019*
<25	91 (28)	66 (25)	19 (32)	
≥25	238 (72)	194 (74)	41 (68)	
Data absent	1 (0)	1 (0)	0 (0)	
KPS (%)	90 (80 - 90)	90 (80 - 90)	80 (80 - 90)	<0.001*
Diagnosis				
Plasma cell disorders	**236 (72)**	**188 (72)**	**42 (70)**	
Multiple Myeloma	228 (69)	182 (70)	40 (67)	
Amyloidosis	6 (2)	4 (2)	2 (3)	
POEMS	2 (1)	2 (1)	0 (0)	
Lymphoma	**84 (26)**	**65 (25)**	**16 (27)**	
Hodgkin Disease	22 (7)	19 (7)	2 (3)	
NHL	60 (18)	45 (17)	13 (22)	
CLL	1 (0)	0 (0)	1 (2)	
PTLD	1 (0)	1 (0)	0 (0)	
Other	**10 (3)**	**8 (3)**	**2 (3)**	
Germ Cell	6 (2)	5 (2)	1 (2)	
AML	3 (1)	2 (1)	1 (2)	
APML	1 (0)	1 (0)	0 (0)	
Time from Diagnosis (years)	0.8 (0.5 - 1.7)	0.8 (0.5 - 1.7)	0.8 (0.5 - 2.2)	0.900
Previous Lines of Therapy	2 (1 - 2)	2 (1 - 2)	2 (1 - 3)	0.177
1	143 (43)	117 (45)	24 (40)	
2	121 (37)	96 (37)	20 (33)	
3	21 (6)	17 (7)	4 (7)	
4+	43 (13)	29 (11)	12 (20)	
ASCT				
First ASCT	304 (92)	245 (94)	51 (85)	0.021*
Repeat ASCT	26 (8)	16 (6)	9 (15)	

Transplant-associated weight loss				
Weight loss (%)	5.4 (3.2 - 7.7)	5.5 (3.2 - 7.6)	4.8 (2.3 - 8.4)	0.452
High	100 (30)	81 (31)	16 (27)	
Low	223 (68)	178 (68)	41 (68)	
Data absent	7 (2)	2 (1)	3 (5)	

* $p < 0.05$ in High versus Low Malnutrition Risk Patients

Table 2. Differences in clinical outcomes relative to malnutrition risk

Outcome	High malnutrition risk (n = 60)	Low malnutrition risk (n = 261)	p-value	High malnutrition risk, univariate OR (95% CI)	High malnutrition risk, multivariate OR (95% CI)
Length of Stay, days, median (IQR)	15 (13 - 18)	13 (12 - 16)	0.004*		
Time to Neutrophil Engraftment, days, median (IQR)	11 (10 - 11)	11 (10 - 12)	0.755		
Time to Platelet Engraftment, days, median (IQR)	20 (18 - 24)	19 (17 - 21)	0.022*		
Culture-positive infections, n (%)	28 (47)	70 (27)		2.387 (1.342 - 4.249) p = 0.003*	1.912 (1.008 - 3.628) p = 0.047*
ICU transfer, n (%)	8 (13)	17 (7)		2.208 (0.905 - 5.388) p = 0.082	2.007 (0.662 - 6.085) p = 0.218
Deconditioning at discharge, n (%)	21 (35)	45 (17)		2.661 (1.425 - 4.971) p = 0.002*	1.918 (0.920 - 3.999) p = 0.082
30-Day Readmission, n (%)	6 (10)	18 (7)		1.551 (0.587 - 4.097) p = 0.376	1.506 (0.522 - 4.344) p = 0.448
One-year mortality/hospice referral, n (%)	13 (22)	28 (11)		2.487 (1.192 - 5.191) p = 0.015*	2.655 (1.067 - 6.604) p = 0.036*

* indicates $p < 0.05$. Statistical tests were Mann-Whitney U tests and binary logistic regressions. Multivariate models were adjusted for age, sex, KPS, conditioning regimen, and repeat SCT.

Table 3. Differences in clinical outcomes relative to weight loss

Outcome	High Weight Loss (n = 100)	Low Weight Loss (n = 223)	p-value	High weight loss, univariate OR (95% CI)	High weight loss, multivariate OR (95% CI)
Length of Stay, days, median (IQR)	15 (13 - 19)	13 (12 - 15)	<0.001*		
Time to Neutrophil Engraftment, days, median (IQR)	11 (10 - 11)	11 (10 - 12)	0.434		
Time to Platelet Engraftment, days, median (IQR)	19 (17 - 22)	19 (18 - 22)	0.789		
Culture-positive infections, n (%)	30 (30)	65 (29)		1.042 (0.622 - 1.745) p = 0.877	1.068 (0.612 - 1.865) p = 0.816
ICU transfer, n (%)	14 (14)	8 (4)		4.375 (1.772 - 10.803) p = 0.001*	6.085 (2.192 - 16.894) p = 0.001*
Deconditioning at discharge, n (%)	26 (26)	39 (18)		1.685 (0.957 - 2.969) p = 0.071	1.718 (0.897 - 3.292) p = 0.103
30-Day Readmission, n (%)	7 (7)	19 (9)		0.808 (0.328 - 1.989) p = 0.643	0.857 (0.315 - 2.332) p = 0.763
One-year mortality/hospice referral, n (%)	12 (12)	28 (13)		0.906 (0.440 - 1.867) p = 0.790	0.904 (0.365 - 2.238) p = 0.827

* indicates $p < 0.05$. Statistical tests were Mann-Whitney U tests and binary logistic regressions. Multivariate models were adjusted for age, sex, KPS, conditioning regimen, and repeat SCT.

Figure 1. Malnutrition Screening Tool[6]

Have you lost weight recently without trying?	
No	0
Unsure	2
If yes, how much weight (kg) have you lost?	
1-5	1
6-10	2
11-15	3
>15	4
Unsure	2
Have you been eating poorly due to a decreased appetite?	
No	0
Yes	1

Figure 2. MST Score Distribution