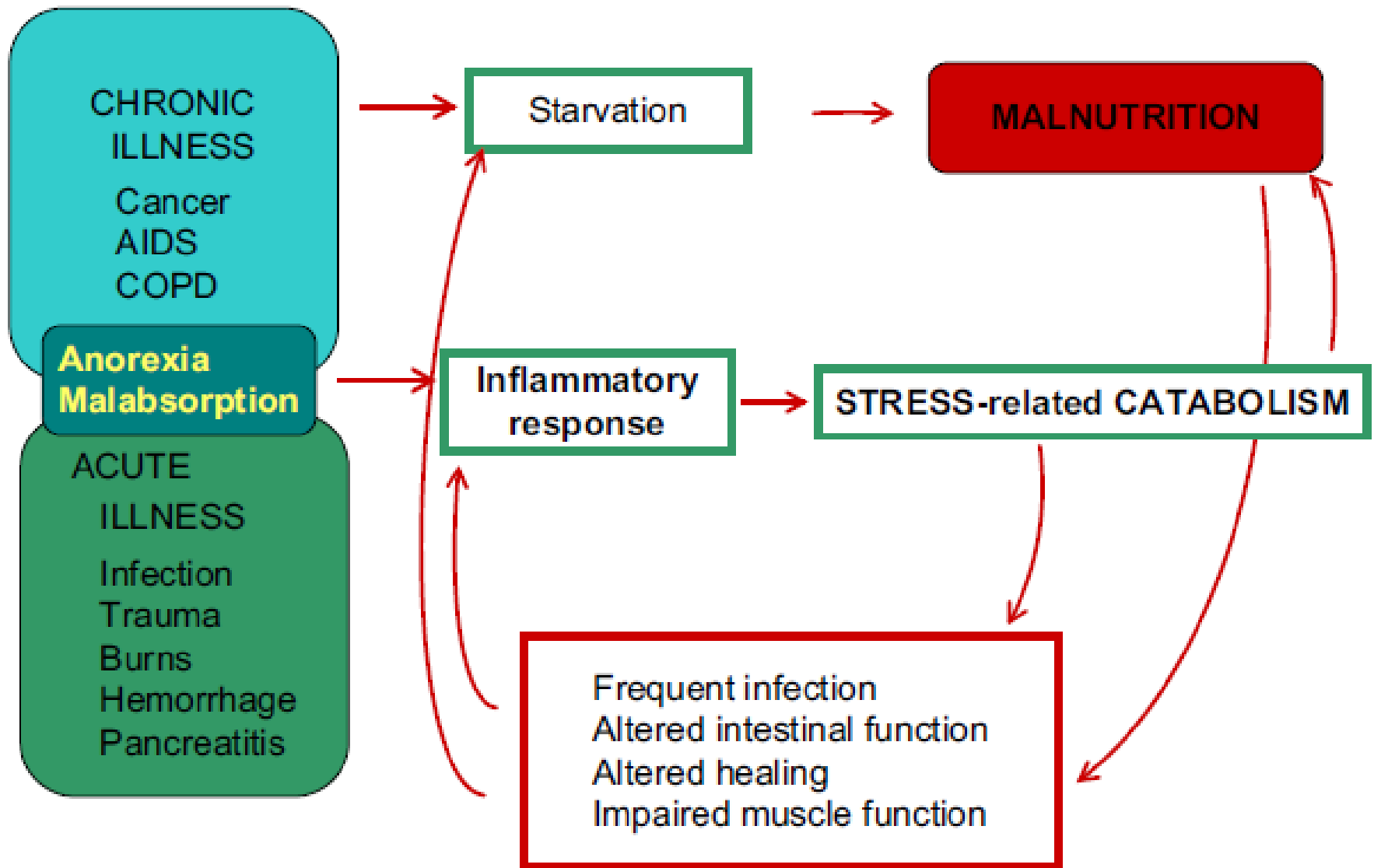


A retrospective study assessing the prevalence of malnutrition and its impact on the clinical outcome after allogeneic hematopoietic stem cell transplantation

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Impact of malnutrition



Body mass index in patients with cGVHD

Table 3 Body-mass index of 93 patients according to chronic graft-versus-host disease classification^a

<i>BMI stratum</i>	<i>Inactive cGVHD n (%)</i>	<i>Active cGVHD n (%)</i>	<i>Total n (%)</i>
<18.5	1 (4)	12 (17)	13 (14)
18.5–21.9	7 (30)	20 (29)	27 (29)
22.0–24.9	3 (13)	24 (34)	27 (29)
>24.9	12 (53)	14 (20)	26 (28)
Total	23 (100)	70 (100)	93 (100)

^a*P* for trend difference = 0.02.

Weight loss and symptoms

Table 5 Symptoms in 69 patients with chronic graft-versus-host disease stratified by weight category

	Weight gain/<5% loss <i>n (%)</i> ^a	5–10% weight loss <i>n (%)</i> ^a	>10% weight loss <i>n (%)</i> ^a	Total <i>n (%)</i> ^a
Active cGVHD	20 (63)	6 (75)	24 (83)	50 (72)
Dysphagia	8 (25)	5 (63)	13 (45)	26 (38)
				(<i>P</i> = 0.08)
Odynophagia	5 (16)	1 (13)	4 (14)	10 (14)
Nausea	14 (44)	4 (50)	11 (38)	29 (42)
Anorexia	8 (25)	3 (38)	7 (24)	18 (26)
Abdominal pain	3 (9)	2 (25)	6 (21)	11 (16)
Oral sensitivity ^b	20 (63)	4 (50)	21 (72)	45 (65)
Malabsorption	0 (0)	0 (0)	1 (3)	1 (1)
Skin cGVHD	25 (78)	5 (83)	20 (69)	50 (72)
Nutritional supplementation	9 (28)	3 (50)	21 (72)	33 (48)
				(<i>P</i> < 0.001)
Total	32	8	29	69 (100%)

^aPercentage of patients reporting/having that symptom out of total number of patients in that weight category.

^bDichotomized in this analysis as yes/no.

All *P* values testing differences among groups by chi-square are >0.1 unless specified.

Primary Objective:

The primary objective is to determine the prevalence of malnutrition after allogeneic HSCT. The prevalence is calculated as a proportion of patients with malnutrition within the patients who survived at each time point (**3 months, 6 months, 9 months, 1 year**).

Malnutrition is defined in this study as a loss of body weight as follows;

No malnutrition Body weight loss in 3 months < 5%:

Mild malnutrition Body weight loss in 3 months 5-10%:

Severe malnutrition Body weight loss in 3 months >10%

Secondary Objectives

Secondary objectives are as follows.

1. Probability of overall survival
2. Probability of progression-free survival
3. Cumulative incidence of non-relapse mortality
4. Cumulative incidence of relapse
5. Cumulative incidence of infectious diseases including bacterial, fungal and viral
6. Cumulative incidence and the severity of chronic GVHD.

The association between malnutrition and clinical factors and laboratory factors will be assessed.

Inclusion Criteria

The retrospective analysis will be conducted on data from subjects with the following criteria:

- Diagnosis with one of the following disease;
 - a. Acute myeloid leukemia (AML) in 1st or 2nd complete remission (CR)
 - b. Acute lymphoid leukemia (ALL) in 1st or 2nd CR
 - c. Chronic myeloid leukemia (CML) in 1st chronic phase (CP)
- First HSCT
- * **Patients with a history of either prior allogeneic HSCT or autologous HSCT are excluded.**
- Adults (≥ 18 years old)
- Transplanted from the beginning of January 2000 up to the end of December 2009
- Transplanted from HLA-matched donor
- With the record of body weight pretransplant and at least 2 time points after HSCT
- Who survived at least 3 months without the progression of disease
- * **Those who relapsed later than 3 months after allogeneic HSCT can be included.**