MINUTES
CIBMTR WORKING COMMITTEE FOR GRAFT-VERSUS-HOST DISEASE
Honolulu, HI
Friday, February 14, 2025, 1:00 – 3:00 PM

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Statistician:	**Jakob Devos, MS; CIBMTR® (Center for International Blood and Marrow Transplant Research, Milwaukee, WI; E-mail : jdevos@mcw.edu**

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1. **Introduction**
    a. Minutes from February 2024 (Attachment 1)

2. **Accrual summary** (Attachment 2)

3. **Presentations, Publications or Submitted papers**
    a. **GV18-02** Wallis W, Gulbis AM, Wang T, Wang T, Lee CJ, Sharma A, Williams KM, Nishihori T, Prestidge T, Gowda L, Byrne M, Krem MM, MacMillan ML, Kitko CL, Pidala J, Spellman SR, Lee SJ, Alousi AM. Incidence of bacterial blood stream infections in patients with acute GVHD. **Bone Marrow Transplantation. doi:10.1038/s41409-024-02426-9. Epub 2024 Oct 18.**
    b. **GV21-01/GV22-03** Farhadfar N, Rashid N, Chen K, DeVos JD, Wang T, Ballen KK, Beitinjaneh A, Bhatt VR, Hamilton BK, Hematti P, Gadalla SM, Solomon SR, El Jurdi N, Lee CJ, MacMillan ML, Rangarajan HG, Schoemans HM, Sharma A, Spellman SR, Wingard JR, Lee SJ. Racial, ethnic and socioeconomic diversity and outcomes of patients with graft-versus-host disease: A CIBMTR analysis. **Blood Advances. 2024 Sep 24; 8(18):4963-4976. doi:10.1182/ bloodadvances. 2024013074. Epub 2024 May 24. PMC11496972.**
    c. **GV18-04** Development of a risk score to predict the incidence of acute graft versus host disease after allogeneic hematopoietic cell transplantation. (C Ulschmid). ***Submitted.***
    d. **GV22-01** Graft Vs Host Disease (GVHD) in Pediatric Hematopoietic Stem Cell Transplant (HCT) Recipients and Impact on Overall Survival: A CIBMTR Analysis (M Nishitani/ C Duncan/ R Graham/ M Qayed). ***Oral Presentation, ASH 2024.***

e. **GV21-02** Determinants of successful discontinuation of immune suppression following allogeneic hematopoietic cell transplantation: A validation study (J Pidala/ B Logan/ M Martens). ***Oral Presentation, Tandem 2025.***

4. Studies in progress (Attachment 3)

a. **GV20-01** Machine learning models and clinical decision support tool for acute and chronic graft-versus-host disease in patients with acute myelogenous leukemia undergoing allogeneic transplants (T Kindwall-Keller/ B Lobo). **Analysis.**
b. **GV20-02** Prediction of graft-versus-host disease in recipients of hematopoietic cell transplant from a single mismatched unrelated donor using a highly-multiplexed proteomics assay: MHC-PepSeq (K Sandhu/ J Altin/ M Askar/ R Nakamura). **Manuscript Preparation.**
c. **GV21-02** Determinants of successful discontinuation of immune suppression following allogeneic hematopoietic cell transplantation: A validation study (J Pidala/ B Logan/ M Martens). **Analysis.**
d. **GV22-01** Acute and chronic graft versus host disease in infants and toddlers following hematopoietic cell transplantation (M Nishitani/ C Duncan/ R Graham/ M Qayed). **Manuscript Preparation.**
e. **GV22-02** Chronic GVHD Risk Index: A clinical risk assessment score for development of moderate-severe chronic graft-versus-host disease after hematopoietic cell transplantation (A Im/ S Pavletic). **Manuscript Preparation.**
f. **GV23-01** The effect of CNI- vs. PTCy- (with or without MMF) based GVHD prophylaxis on HLA-matched HCT (R Mehta/ P Munshi/ R Nath/ Z Zhou/ S Mccurdy). **Protocol Development.**
g. **GV23-02** Incidence of chronic graft versus host disease in cryopreserved versus fresh peripheral blood allogeneic hematopoietic stem cell grafts (K Maurer). **Datafile Preparation.**
h. **GV24-01** Post-transplantation cyclophosphamide (PTCy)/ sirolimus versus PTCy/calcineurin-inhibitor-based graft-versus-host disease prophylaxis (R Mehta/ N Bejanyan). **Protocol Development.**
i. **GV24-02** Effect of acute graft-versus-host disease on the outcome of hematopoietic cell transplantation with post-transplantation cyclophosphamide: a CIBMTR analysis (A Hadjis/ S McCurdy). **Protocol Development.**
j. **GV24-03** Differences in the characteristics of acute and chronic graft-versus-host disease after post-transplantation cyclophosphamide versus conventional calcineurin inhibitor-based graft-versus-host disease prophylaxis (R Mehta/ R Saliba). **Protocol Development.**

5. Future/proposed studies

a. **PROP 2409-19** Impact of Ruxolitinib Treatment for Acute GVHD on the Incidence and Severity of Chronic GVHD (A Ali) (Attachment 4)

Dr. Ali from Georgetown University presented.

- *Objective: To assess whether the use of ruxolitinib for acute GVHD reduces the incidence and severity of chronic GVHD.*
- *Key Points:*
  - *Hypothesis: Ruxolitinib in acute GVHD may lower chronic GVHD incidence and severity.*
  - *Study involves 2,315 patients, with 541 receiving ruxolitinib.*
  - *Primary objective: Compare chronic GVHD incidence in ruxolitinib vs. other treatments.*

- *Secondary objectives: Assess severity, organ involvement, steroid responsiveness, and long-term survival.*

- *Discussion:*
  - *Questions about steroid tapering and calcineurin inhibitor impact.*
  - *Concerns about the year of transplant and post-transplant cyclophosphamide (PTCy) impact.*
  - *Also concerns about limited information about duration of ruxolitinib treatment and details about administration.*
  - *Just compare second line ruxolitinib to other agents? Or also look at third, fourth line etc?*
  - *Ruxolitinib was used in more recent transplants and we know the rate of cGVHD is going down.*

b. **PROP 2410-43; 2410-106** Impact of Post-Transplant Cyclophosphamide Dosing on Outcomes of Allogeneic Hematopoietic Cell Transplantation (H Elmariah/ A Rezvani/ C Shultz/ S Yu) (Attachment 5)

- *Objective: To determine the optimal dosing of PTCy for improved overall survival in allogeneic transplants.*
- *Key Points:*
  - *PTCy is standard for GVHD prophylaxis but optimal dosing is unclear.*
  - *Study compares different PTCy doses (100 mg/kg, 60-80 mg/kg, 40-60 mg/kg, <40 mg/kg).*
  - *Primary endpoint: Overall survival.*
  - *Secondary endpoints: Disease-free survival, GVHD incidence, infections, and cardiac toxicities.*
- *Discussion:*
  - *Won't we get the answer about lower dose PTCy from clinical trials like OPTIMIZE?*
  - *Concerns about confounding factors like cardiac toxicities and patient-related factors. Many people are dose-reducing for comorbidities.*
  - *Questions about actual vs. ideal body weight dosing.*
  - *Forms captured PTCy dosing differently – many values do not make sense.*

c. **PROP 2410-254** Abatacept versus post-transplantation cyclophosphamide as GVHD prophylaxis after allogeneic hematopoietic stem cell transplantation for myeloid malignancies (S Mirza/ J Pidala) (Attachment 7)

Dr. Mirza from Moffitt Cancer Center presented.

- *Objective: To compare Abatacept and PTCy for GVHD prophylaxis in myeloid malignancies.*
- *Key Points:*
  - *Abatacept is increasingly used as an alternative to PTCy.*
  - *Retrospective analysis shows no significant difference in overall survival, relapse, or TRM.*
  - *Possible differences in acute and chronic GVHD rates.*
  - *Study focuses on 8/8 and 7/8 mismatched unrelated donors.*

- *Discussion:*
    - *Concerns about age distribution and follow-up times.*
    - *Suggestions to separate adult and pediatric populations for analysis. WC most interested in pediatric use*

d. **PROP 2410-103** Impact of prior chimeric antigen receptor T-cell treatment on graft-vs-host disease and non-relapse mortality after allogeneic hematopoietic cell transplantation (T Othman/ M Al Malki) (Attachment 6)

Dr. Othman from UCSF Medical Center presented.

- *Objective: To assess if prior CAR T-cell therapy increases the risk of GVHD and NRM post-allogeneic transplant.*
- *Key Points:*
    - *CAR T-cells alter the immune environment, potentially increasing GVHD risk.*
    - *Study includes 633 patients with prior CAR T-cell therapy.*
    - *Primary endpoint: Grade 3-4 acute GVHD at day 100.*
    - *Secondary endpoints: Chronic GVHD, NRM, overall survival, and relapse.*
- *Discussion:*
    - *Questions about disease status at transplant and pre-transplant treatments.*
    - *Suggestions to adjust for disease status and consider CRF level data. Patients who get a CAR-T before transplant have aggressive disease.*
    - *Will knowledge that a patient received CAR-T before transplant affect how the transplant is done or how they are managed?*
    - *May be another study in the acute leukemia committee looking at CD19 CAR-T pre and post transplant.*

Proposed studies; not accepted for consideration at this time

e. **PROP 2403-01** Recipient Age, Incidence, Non-Relapse Mortality, and Mortality in Acute and Chronic Graft-vs-Host Disease (W Ciurylo). ***Dropped due to lower scientific impact.***

f. **PROP 2404-02** Rates of GVHD between myeloid and non hodgkin lymphoma patients undergoing Matched Unrelated Allogeneic Transplantation (L Mountjoy). ***Dropped due to lower scientific impact.***

g. **PROP 2408-09** Incidence of Ocular Graft Versus Host Disease (oGVHD) Confirmed by Ophtolmatologists According to CIBMTR Database (M Pamukcuoglu). ***Dropped due to lower scientific impact.***

h. **PROP 2408-10** Has an Acute Graft Versus Host Disease Severity, Impact Chronic Graft Versus Host Disease Severity? (M Pamukcuoglu). ***Dropped due to overlap with current study/publication.***

i. **PROP 2409-23** Post-transplant cyclophosphamide impact on survival and graft versus host disease in female-to-male allogeneic hematopoietic cell transplantation (A Law/ S Rodriguez). ***Dropped due to overlap with current study/publication.***

j. **PROP 2410-21** Comparing Outcomes Between HLA-Haploidentical and Mismatched Unrelated Donor Transplantation Among Patients Receiving Reduced Intensity Conditioning With Posttransplant Cyclophosphamide-Based Graft Versus Host Disease Prophylaxis (V Agrawal/ M Al Malki). ***Dropped due to overlap with current study/publication.***

k. **PROP 2410-24** Impact of Renal and Cardiac Function on the Selection of Graft-Versus-Host Disease Prophylaxis Strategies in Hematopoietic Cell Transplantation (R Shouval/ M Perales). ***Dropped due to supplemental data needed.***
l. **PROP 2410-33** Outcomes in patients above the age of 70 undergoing allogeneic transplant for Acute Myeloid leukemia with post-transplant Cyclophosphamide (M R Pandey/ Y Lei). ***Dropped due to overlap with current study/publication.***
m. **PROP 2410-90** Comparison of ATG vs PTCy based GVHD prophylaxis regimens in Allogeneic stem cell transplant using HLA matched unrelated and mismatched unrelated donors (R V Nampoothiri). ***Dropped due to overlap with current study/publication.***
n. **PROP 2410-151** Clinical Outcomes of sex mismatch allogeneic hematopoietic stem cell transplant with the use of post-transplant cyclophosphamide for graft-versus-host disease prophylaxis in Acute Myeloid Leukemia and Myelodysplastic Syndrome (G Kaleka/ A Socola). ***Dropped due to overlap with current study/publication.***
o. **PROP 2410-159** Chronic GVHD Risk Index: A clinical risk assessment score for development of moderate-severe chronic graft-versus-host disease (GVHD) after hematopoietic cell transplantation (HCT) (A Ramgopal/ S Pavletic). ***Dropped due to overlap with current study/publication.***
p. **PROP 2410-163** Outcomes of Unmodified Allogeneic Hematopoietic Transplantation With Calcineurin-Inhibitor-Free GVHD Prophylaxis (G Raju/ D Ponce). ***Dropped due to supplemental data needed.***
q. **PROP 2410-250** Impact of post-transplantation cyclophosphamide (PTCy) on graft-versus-host disease and relapse after subsequent donor lymphocyte infusion (M Hyder/ C Kanakry). ***Dropped due to supplemental data needed.***