

MINUTES AND OVERVIEW PLAN CIBMTR WORKING COMMITTEE FOR LYMPHOMA Orlando, FL

Wednesday, February 19, 2020 12:15-2:45 pm

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1. Introduction

The CIBMTR Hodgkin and Non-Hodgkin Lymphoma Working Committee was called to order at 12:15 pm on Wednesday, February 19, 2020 by Dr. Mehdi Hamadani. Dr. Tim Fenske introduced the working committee leadership, and highlighted leadership's conflict of interest disclosures per CIBMTR policy. Dr. Fenske also outlined the Working Committee goals, expectations, and limitations and provided an update on the Working Committee productivity including 3 publications, 2 recent submissions, 3 oral presentations at the 2019 American Society of Hematology meeting, and 1 oral presentation at the 2020 EBMT meetings. Dr. Mohamed Kharfan-Dabaja went over the six studies in progress and reviewed the voting guidelines. The guidelines are based on a scale from 1 to 9; 1=high scientific impact, 9=low scientific impact. In addition, Dr. Kharfan-Dabaja presented the future priority of our studies. Dr. Mehdi Hamadani explained the difference between the TED and CRF data collection forms, the study life cycle, and the rules for authorship: 1) substantial and timely contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; 3) final approval for the version to be published. Dr. Hamadani emphasized that WC authorship is open to any LYWC Tandem Meetings attendees and encouraged junior faculty, fellows and assistant professors to collaborate actively with the Lymphoma Writing Committee. Dr. Hamadani reviewed the Advisory Committee metrics for the committee, especially highlighting the lack of any manuscripts in preparation for more than one year and no studies in progress for more than 3 years. He also highlighted the committee's highest cited paper in the last five years: Reduced-intensity transplantation for lymphomas using haploidentical related donors vs HLA-matched unrelated donors (Kanate et al, Blood 2016). Dr. Hamadani finished the introduction slides by thanking Dr. Fenske for his work with the committee, as Dr. Fenske's term as Chair is ending. Dr. Fenske welcomed the incoming Chair, Dr. Alex Herrera.

2. Accrual summary

Dr. Mohamed Kharfan-Dabaja presented a slide with the accruals. It was mentioned that the accrual summary was available in the LYWC materials, attachment 2.

3. Presentations, published or submitted papers

Dr. Mohamed Kharfan-Dabaja listed the presentations and publications during 2018, highlighting the great productivity of the LYWC, including the following studies published or presented:

- a. **LY17-01b** Allogeneic transplantation in elderly patients ≥65 years with non-Hodgkin lymphoma: a time-trend analysis. (N Shah) *Published in Blood Cancer Journal. Oral presentation at the 2019 EBMT Annual Meeting.*
- b. **LY17-02a** Impact of type of reduced-intensity conditioning regimen on the outcomes of allogeneic hematopoietic cell transplantation in classical Hodgkin lymphoma. *Submitted. Presented at ASH Annual Meeting.*
- c. **LY17-02b** Evaluating impact of reduced-intensity conditioning regimens on overall survival in non-Hodgkin lymphoma patients undergoing allogeneic transplantation. A CIBMTR registry analysis. *Submitted. Oral presentation at the ASH Annual Meeting.*
- d. **LY17-02c** Higher total body irradiation dose-intensity in fludarabine/TBI-based reduced-intensity conditioning regimen is associated with inferior survival in non-Hodgkin lymphoma patients undergoing allogeneic transplantation. *Submitted*.
- e. **LY17-02d** Reduced intensity conditioning in allografts for diffused large B-cell lymphoma (Internal) *Oral presentation at the upcoming 2020 EBMT Annual Meeting.*
- f. **LY18-01** Outcomes of rituximab-BEAM vs. BEAM conditioning regimen in patients with diffuse large B-cell lymphoma undergoing autologous transplantation. (D Jagadeesh) *Submitted. Oral presentation at the ASH Annual Meeting.*

4. Studies in progress

Dr. Mohamed Kharfan-Dabaja presented the studies in progress and gave an overview of the current standing of each study.

- a. **LY17-02d** 2 versus 4 centigray fludarabine/total body irradiation in allografts for non-hodgkin lymphoma (Internal) **Manuscript Preparation**
- b. **LY18-01b** Outcomes in b cell non-hodgkin's lymphoma patients who underwent autologous stem cell transplantation following rituximab containing conditioning regimens in partial remission (Internal) **Manuscript Development**
- c. **LY18-02** Effect of time to relapse on overall survival in mantle cell lymphoma patients following frontline autologous stem cell transplant (P Riedell/S Smith) **Data file preparation**
- d. **LY18-03** Transplantation for CLL undergoing Richter's Transformation arising in the setting of indolent lymphoma (A Herrera) **Data accrual**
- e. **LY19-01** Post-transplant cyclophosphamide-based haploidentical transplantation versus matched sibling or well-matched unrelated donor transplantation for peripheral T-cell lymphoma: A CIBMTR Lymphoma working committee and EBMT Lymphoma working party analysis (P Dreger/M Hamadani) **Data file preparation**
- f. LY19-02 Determining the optimal conditioning regimen for patients with primary central nervous system lymphoma undergoing autologous hematopoietic cell transplantation (M Scordo/C Sauter/A Jimenez) Protocol Development

5. Introduction to TED (Transplant Essential Data) vs CRF (Comprehensive Report Form) (M Hamadani)

Dr. Mehdi Hamadani emphasized the difference between the TED and CRF databases. It was emphasized that CRF is a subset of the TED database, and that the CRF forms collect all disease specific information such as lines of therapy, extranodal involvement, and prior radiation. If a study needs any of this information, CRF level data is needed on the study.

6. Future/proposed studies

- a. **PROP 1911-51** CAR-T cell Therapy versus Autologous Transplant in Early Rituximab Failure Patients with Diffuse Large B-cell Lymphoma (Shah) (Attachment 4) *This concept intends to compare overall survival following autologous HCT and CAR-T among patients with frontline Rituximab failure. During discussion, it was mentioned that a limitation of the study will be patients who fail autologous transplants and move on to receive CAR-T, and Dr. Shah agreed that exclusion of patients with prior transplants is important.*
- b. **PROP 1911-22** Outcomes of hematopoietic stem cell transplant as treatment of post-transplant lymphoproliferative disorders (Farhan) (Attachment 5) *This concept intents to study outcomes after autologous HCT for patients with PTLD. Dr. Hamadani explained that PTLD was only added as a distinct histology to CIBMTR forms in 2018, which explains why 70% of the eligible patients were transplanted in 2018. Additionally, it was discussed that looking at pre-HCT treatment would be important, but since there were few CRF-level cases, that data would be limited.*
- c. **PROP 1911-88** Outcomes of autologous and allogeneic hematopoietic cell transplantation for Burkitt Lymphoma (Hashmi, Khimani, Nishihori) (Attachment 6) *This concept intends to study outcomes after HCT for Burkitt Lymphoma. It was mentioned during discussion that it would be important to confirm cases are true Burkitt's, and not Burkitt-like. Dr. Hamadani also emphasized that this would likely be a descriptive analysis, as comparing autologous and allogeneic HCTs is often difficult.*
- d. **PROP 1911-93** Evaluating outcomes of Hematopoietic Cell Transplantation in Hepatosplenic T Cell Lymphoma (Murthy, Iqbal, Kharfan-Dabaja) (Attachment 7) *This concept intends to study the outcomes after allogeneic HCT for patients with hepatosplenic T-cell lymphoma. It was asked why autologous HCTs would not be included in the analysis, and it was explained that the proposal team limited the analysis to autologous on recommendation from committee leadership due to inadequate number of autos. Additionally, it was mentioned that information on splenectomies would be important, and Dr. Hamadani explained that data would be available at the CRF level only.*
- e. **PROP 1911-267** Comparison of outcomes of DLBCL patients with partial response after salvage therapy who underwent CAR-T vs. ASCT. (Shadman) (Attachment 8) *This concept intends to compare CAR-T and autologous HCT as salvage therapy in DLBCL patients with partial response. During the discussion, it was mentioned that this is an important question for the field, and that it is answerable by the CIBMTR. It was suggested that there could be variability in partial response, and that it would be important to adjust for disease characteristics.*
- f. **PROP 1910-01/1911-61/1911-185** Outcomes of salvage AHCT in double hit DLBCL (Manjappa, Karmali, Wirk, Caimi, Metheny) (Attachment 9) *This concept intends to determine the effect of disease status and chemosensitivity of relapsed/refractory DHL on outcomes after autologous HCT. During discussion, it was asked if double expressor lymphoma could be included, which Dr. Hamadani clarified was not captured by the CIBMTR forms and therefore could not.*
- g. **PROP 1911-256** Outcome of Patients with Primary Refractory Diffuse large B cell lymphoma (DLBCL) undergoing Autologous Stem Cell Transplantation (AHCT) (Bal, Sauter, Costa)

(Attachment 10) This concept intends to study the outcomes after autologous HCT for patients with primary refractory DLBCL. There was discussion on the definition of primary refractory.

- h. **PROP 1911-121** Outcomes of autologous stem cell transplantation in patients with follicular lymphoma with early relapse after frontline Bendamustine/Rituximab treatment. (Sheikh, Keating, Kuruvilla) (Attachment 11) This concept intends to study the effect of POD24 after frontline Bendamustine/Rituximab on outcomes after autologous HCT. It was mentioned that a collaboration with EBMT could improve the number of patients in the study.
- i. **PROP 1911-42** Outcomes of Allogeneic HCT in patients with Hodgkin Lymphoma in the era of Checkpoint Inhibitors: A joint CIBMTR and EBMT analysis. (Perales, Sureda, Awan, Montoto) (Attachment 12) *This concept intends to compare the use of checkpoint inhibitors on outcomes after allogeneic HCT for Hodgkin Lymphoma. It was brought up that time from checkpoint inhibitor use to HCT would be an important factor. It was also suggested that a comparison of BM and PBSC might be useful, though there was concern about sample size.*
- j. **PROP 1911-204** Trends in Survival post-autologous transplant in Classical Hodgkin Lymphoma. (Shah) (Attachment 13) *This concept intends to study overall survival following autologous HCT for classical HL. It was mentioned that perhaps looking at drug approval dates as cutoffs might be useful. For example, using Brentuximab's approval date of 2011 as a cutoff.*

Proposed studies; not accepted for consideration at this time

- a. **PROP 1909--04** Outcomes of allogeneic stem cell transplantation with different donor types for patients with lymphomas not in remission at the time of transplant.
- b. **PROP 1910-02** Optimizing timing of autologous transplantation for transformed follicular lymphoma.
- c. **PROP 1911-11** Efficacy of allogeneic transplant in marginal zone lymphoma.
- d. **PROP 1911-22** Outcomes of hematopoietic stem cell transplant as treatment of post-transplant lymphoproliferative disorders.
- e. **PROP 1911-28** Outcomes of relapsed/refractory lymphoma patients treated with benda-EAM (bendamustine, etoposide, cytarabine, melphalan) versus BEAM (carmustine, etoposide, cytarabine, melphalan) high dose chemotherapy followed by autologous stem cell transplantation.
- f. **PROP 1911-32** Impact of pre-transplant induction therapy on outcomes of patient who undergo autologous stem cell transplantation for mantle cell lymphoma in CR1.
- g. **PROP 1911-47** Hematopoietic stem cell transplantation for relapsed/refractory marginal zone lymphoma.
- h. **PROP 1911-70** Clinical impact of partial remission versus complete remission on outcomes in follicular lymphoma after autologous stem cell transplantation.
- i. **PROP 1911-72** Determination of outcomes of upfront consolidative autologous stem cell transplantation in patients with high FLIPI score follicular lymphoma.
- j. **PROP 1911-85** Outcomes of allogeneic hematopoietic cell transplantation for mycosis fungoides and Sezary syndrome.
- k. **PROP 1911-87** Outcomes of autologous and allogeneic hematopoietic cell transplantation for primary mediastinal large B-Cell lymphoma.
- l. **PROP 1911-98** Evaluating the efficacy of high-dose therapy and autologous hematopoietic cell transplantation for primary effusion lymphoma.
- m. **PROP 1911-101** Outcomes of patients with mantle cell lymphoma with aberrant TP53 treated with consolidative autologous or allogeneic stem cell transplant.

- n. **PROP 1911-126** Outcomes in elderly patients (age ≥ 70) received autologous hematopoietic stem cell transplantation for non-Hodgkin lymphoma.
- PROP 1911-136 Matched versus alternative donor allogeneic hematopoietic stem cell transplantation in HTLV-1 associated adult T-cell lymphoma/leukemia in patients of non-Japanese descent.
- p. **PROP 1911-151** Outcomes of reduced intensity allografts in classical Hodgkin lymphoma after brentuximab maintenance therapy.
- q. **PROP 1911-157** Outcomes of patients ≥ 65 years old undergoing autologous stem cell transplant for mantle cell lymphoma.
- r. **PROP 1911-192** Outcomes following allogeneic hematopoietic stem cell transplantation for mycosis fungoides and Sezary syndrome.
- s. **PROP 1911-208** Autologous stem cell transplantation for HIV seropositive patients with hematological malignancies.
- t. PROP 1911-222 Utilization and outcomes of autologous and allogeneic HSCT in CNS lymphomas.
- u. **PROP 1911-227** Outcomes of patients with HTLV-1 associated adult T cell lymphoma/leukemia: A combined American and European experience.
- v. **PROP 1911-229** Effect of mobilization agent on risk of second hematological malignancy in patients with lymphoma who received autologous transplant.
- w. **PROP 1911-231** Outcome of autologous and allogeneic hematopoietic cell transplant in marginal zone lymphoma.
- x. **PROP 1911-239** High dose therapy and autologous stem cell transplantation in primary central nervous lymphoma in older adults.
- y. **PROP 1911-244** Impact of pre- and post-transplantation lymphopenia and 18F-fluorodeoxy glucose—positron emission tomography status on outcomes after autologous hematopoietic cell transplantation for peripheral T-cell lymphoma.
- z. **PROP 1911-257** Outcome of autologous hematopoietic stem cell transplant in older patients (age >70 years) with non-Hodgkin's lymphoma.

7. Other Business

After the proposals were presented, the voting process was reiterated, and each participant had the opportunity to rate each new proposal using paper ballots. Without additional comments, the meeting was adjourned at 2:05 pm.

Working Committee Overview Plan for 2020-2021

Study number and title	Current status	Goal with date	Total hours to complete	Total hours to goal 7/1/2020	Hours allocated to 6/30/2020	Hours allocated 7/1/2020- 6/30/2021	Total Hours allocated
LY17-02a: Allografts following reduced intensity conditioning for hodgkin's lymphoma.	Submitted	Published – May 2020	10	10	10	0	10
LY17-02b: Allografts following reduced intensity conditioning for non-hodgkin disease.	Submitted	Published – May 2020	10	10	10	0	10
LY17-02d: 2 versus 4 centigray fludarabine/total body irradiation in allografts for non-hodgkin lymphoma	Manuscript preparation	Submitted – June 2020 Published – July 2021	20	20	10	10	20
LY18-01a: Outcomes in b cell non-hodgkin's lymphoma patients who underwent autologous stem cell transplantation following rituximab containing conditioning regimens	Submitted	Published – July 2020	10	10	10	0	10
LY18-01b: Outcomes in b cell non-hodgkin's lymphoma patients who underwent autologous stem cell transplantation following rituximab containing conditioning regimens in partial remission	Manuscript preparation	Submitted – July 2020 Published – July 2020	50	60	50	10	60
LY18-02: Effect of time to relapse on overall survival in mantle cell lymphoma patients following frontline autologous stem cell transplant.	Data file preparation	Analysis – June 2020 Manuscript preparation – July 2020 Submitted – July 2021	160	160	90	70	160

LY18-03: Transplantation for CLL undergoing Richter's transformation arising in the setting of indolent lymphoma.	Data file preparation	Analysis – July 2020 Manuscript preparation– September 2020 Submitted – July 2021	220	220	70	150	220
LY19-01: Post-transplant cyclophosphamide-based haploidentical transplantation versus matched sibling or well-matched unrelated donor transplantation for peripheral T-cell lymphoma: a CIBMTR lymphoma working committee and EBMT lymphoma working party analysis.	Protocol development	Submitted – June 2021	160	160	90	70	160
LY19-02: Determining the optimal conditioning regimen for patients with primary central nervous system lymphoma undergoing autologous hematopoietic cell transplantation.	Draft protocol received	Data file preparation – July 2020 Analysis – October Manuscript preparation – July 2021	330	260	100	160	260
LY20-01: comparison of outcomes of DLBCL patients with partial response after salvage therapy who underwent CAR-T vs. Autologous HCT	Protocol pending	Analysis – May 2021 Manuscript preparation – July 2021	330	260	0	260	260

LY20-02: Outcomes of allogeneic HCT in	Protocol	Protocol	370	100	0	100	100
patients with Hodgkin lymphoma in the era	pending	development – December 2020					
of checkpoint inhibitors: A joint CIBMTR and EBMT analysis							
		Data file					
		preparation –					
		July 2021					

Oversight Assignments for Working Committee Leadership (March 2019)

Craig Sauter	LY18-0	01b Ou	tcom	nes in	b cell ı	non-h	odgkin	's lym	phoma pati	ents w	ho ur	nderwent autologo	us

stem cell transplantation following rituximab containing conditioning regimens

LY19-02 Determining the optimal conditioning regimen for patients with primary central nervous system lymphoma undergoing autologous hematopoietic cell transplantation.

Mohamed Kharfan-Dabaja LY17-02d 2 versus 4 centigray fludarabine/total body irradiation in allografts for non-hodgkin lymphoma

LY18-02 Effect of time to relapse on overall survival in mantle cell lymphoma patients following frontline autologous stem cell transplant.

Alex Herrera LY18-03 Transplantation for CLL undergoing Richter's transformation arising in the setting of indolent lymphoma.

LY20-02 Outcomes of allogeneic HCT in patients with Hodgkin lymphoma in the era of checkpoint inhibitors: A joint CIBMTR and EBMT analysis

Mehdi Hamadani

LY19-01 Post-transplant cyclophosphamide-based haploidentical transplantation versus matched sibling or well-matched unrelated donor transplantation for peripheral T-cell lymphoma: a CIBMTR lymphoma working committee and EBMT lymphoma working party analysis.

LY20-01 Comparison of outcomes of DLBCL patients with partial response after salvage therapy who underwent CAR-T vs. Autologous HCT