

Racial Disparity in Myeloablative Hematopoietic Cell Transplantation Outcomes in Patients with Hematological Malignancies Older Than 45 Years

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Abstract

Introduction: The impact of race on outcomes of allogeneic hematopoietic cell transplants (HCT) has long been a field of research. The Center for International Blood and Marrow Transplant Research (CIBMTR) studies have shown worse survival for Black and Hispanic patients within the first year after HCT, but rates evened out for one-year survivors. From our personal experience, we hypothesize that the outcomes of South Asians (age ≥ 45 years) receiving myeloablative conditioning (MAC) are also worse compared to other races.

Methods: This is a retrospective single-centre study. All patients (age ≥ 45 years) undergoing MAC-HCT for hematological malignancies from 2011-2022 were included. The primary outcome was overall survival (OS). Secondary outcomes were non-relapse mortality (NRM), incidence of grade 2-4 acute graft versus host disease (GVHD), moderate-severe chronic GVHD and relapse incidence (RI). The survival analysis was performed using Kaplan-Meier analysis and log-rank test. The GVHD, NRM and RI rates were calculated using the cumulative incidence (CI) of competing events and the Gray test. EZR was used for statistical analysis.

Results: Of the 483 patients included, there were 28 (5.8%) South Asians (SA), 73 (15.1%), other Asians (East Asians (EA)/Southeast Asians (SEA), and 382 (79.1%) Whites (W). Asians were less likely to get matched unrelated donor-HCT than Whites (SA 21%, EA/SEA 30%, W 45%, $p=0.009$). The three groups were comparable regarding the recipient and donor sex and performance status. The proportion of SA with HCT-CI ≥ 3 was significantly higher (SA 50%, EA/SEA 37%, W 31%, $p=0.03$). SA patients were more likely to be obese (body mass index ≥ 30 kg/m²) (SA 29%, EA/SEA 5%, W 19%, $p=0.005$). There were fewer cytomegalovirus (CMV) serological mismatches among the Asians (SA 25%, EA/SEA 26%, W 43%, $p=0.009$). There was no difference in the conditioning type and CD34 cell dose. However, fewer Asians received Antithymocyte globulin/post-transplant cyclophosphamide as GVHD prophylaxis (SA 39%, EA/SEA 42%, W 45%, $p=0.0009$). The median OS was significantly shorter in SA (SA 19, EA/SEA 103, W 65 months, $p=0.04$). The 2-year NRM was significantly higher in SA (SA 35.7%, EA/SEA 13.7%, W 16%, $p=0.03$). The CI of grade 2-4 acute and moderate-severe chronic GVHD was not significantly different ($p=0.7$ & 0.6). The 2-year RI was also not significantly different (SA 28.5%, EA/SEA 24.7%, W 28%, $p=0.8$).

Conclusion: Our study confirms that South Asians aged ≥ 45 years have worse survival after MAC-HCT. Supportive care is unable to overcome the differences in the outcomes.

Key words racial disparity, myeloablative HCT, age ≥ 45

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Introduction

Allogeneic hematopoietic cell transplantation (HCT) is a potentially curative treatment for hematological malignancies. Myeloablative conditioning (MAC) is generally preferred whenever possible to reduce the risk of relapse in acute leukemia¹. While the organ function criteria, comorbidity index, and performance status cut-offs are similar across centers, the age cutoff to offer MAC varies, typically ranging from 55 to 65^{2,3}. Given the absence of validated tools for frailty/geriatric assessment in HCT, the evaluation of physiologic age remains subjective. The effects of race as both a genetic and socio-economic construct on HCT outcomes have yielded mixed results. The Centre for International Blood and Marrow Transplant Research (CIBMTR) studies have indicated that survival rates are worse for Black and Hispanic patients compared to White and Asian patients within the first year after HCT in the US. However, the survival rates eventually equalize for those who survive beyond one year^{4,6}. Other studies have shown that race has no impact on HCT outcomes^{7,8}. However, most of these studies have included adult patients regardless of age and were performed in resource-rich centers. Studies done in the South Asian population have acknowledged the challenges associated with MAC regimens and have shown worse overall survival and higher mortality with these regimens compared to reduced intensity conditioning (RIC)^{9,10}. In most centers in India, the age cutoff for offering MAC is 45 years. The biological reasons for this are not entirely clear. The influence of socioeconomic factors and supportive care on outcome differences also requires further investigation. We hypothesize that the outcomes for South Asians aged 45 and older receiving a MAC regimen for hematological malignancies are worse compared to other populations, even when treated in a public funded universal healthcare system with centralized uniform treatment criteria.

Materials and Methods

This retrospective single-centre study was conducted at The Leukemia/Bone Marrow Transplant Program of British Columbia, Vancouver, Canada. We included all patients (age ≥ 45 years) undergoing myeloablative conditioning for hematological malignancies from January 2011 to December 2022. Institutional Research Ethics Board approval was obtained before the study. Myeloablative conditioning included total body irradiation (TBI) ≥ 8 Gy fractionated or Busulfan > 6.4 mg/kg IV¹¹. Chemotherapy dosing was as per adjusted body weight 50 if the actual body weight was more than ideal. Baseline patient characteristics (age, sex, race,

body mass index (BMI), hematopoietic cell transplantation-comorbidity index (HCT-CI), performance status, disease, and disease status before transplant), transplant details (donor details, cytomegalovirus (CMV) matching, blood group matching, date of transplant, conditioning regimen, graft versus host disease (GVHD) prophylaxis, and stem cell dose) and events (acute and chronic GVHD, death, and relapse) were recorded. GVHD prophylaxis included standard calcineurin inhibitor (CNI) + methotrexate-based prophylaxis for matched sibling donor (MSD) - and matched unrelated donor (MUD) - HCT. Rabbit Antithymocyte globulin (ATG) (Thymoglobulin[®]; Sanofi-Aventis, Laval, Canada) was added for GVHD prophylaxis for MUD-HCT from 2016 and MSD-HCT from 2018 onwards. The GVHD prophylaxis for haploidentical HCT included post-transplant cyclophosphamide + CNI + mycophenolate. Race was self-reported by the patient and classified as per the CIBMTR definition and guidance on using standards for race-based data collection and health reporting in Canada¹². The primary outcome was overall survival (OS). OS was defined as the time from the day of hematopoietic infusion to death from any cause or last documented follow-up. Secondary outcomes were non-relapse mortality (NRM), cumulative incidence of grade 2-4 acute GVHD (graded as per CIBMTR consensus criteria), moderate-severe chronic GVHD (graded as per National Institutes of Health consensus criteria) and relapse incidence (RI) with relapse as the competing risk. The baseline and the transplant characteristics were compared between cohorts using the Mann-Whitney, chi-square or Fisher's exact test. The survival analysis was done using Kaplan-Meier analysis and log-rank test. The GVHD, NRM, and RI rates were calculated using the cumulative incidence of competing events and the Gray test. A *p*-value of < 0.05 was used for statistical significance. The variables significant at *p*-value < 0.05 in the univariate analysis were included in the multivariable Cox regression model for mortality. EZR was used for statistical analysis¹³. Approval was obtained from the University of British Columbia—BC Cancer Research Ethics Board (UBC BC Cancer REB)(H24-00426, March 11, 2024). The IRB approved the study without needing informed consent from each participant. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

Results

Of the 483 patients, there were 28 (5.8%) South Asians (SA), 73 (15.1%), East/Southeast Asians (EA/SEA), and 382 (79.1%) Whites (W). The median age of the whole cohort was 56 years (range 46-69 years). The

Table 1. Comparison of baseline characteristics

Factor	Group	South Asians (n=28), n (%)	Other Asians (n=73), n (%)	Whites (n=382), n (%)	p-value
Patient characteristics					
Age (years)	< 60	22 (79)	63 (86)	254 (66)	0.001
	≥ 60	6 (21)	10 (14)	128 (34)	
Age (years)	Median (range)	55 (46-65)	52 (46-65)	57 (46-69)	< 0.0001
Sex	Males	16 (57)	38 (52)	223 (58)	0.6
	Females	12 (43)	35 (48)	159 (42)	
Body mass index (kg/m ²)	≥ 25	15 (54%)	28 (38%)	198 (52%)	0.09
	≥ 30	8 (29%)	4 (5%)	74 (19%)	0.005
Performance status	≥ 2	1 (4)	4 (5)	12 (3)	0.6
Comorbidity index	≥ 3	14 (50)	27 (37)	118 (31)	0.03
Diagnosis	ALL	5 (18)	11 (15)	43 (11)	0.5
	AML	15 (54)	35 (48)	174 (46)	
	MDS/MPN	4 (14)	12 (16)	103 (27)	
	Chronic leukemia/lymphoma	4 (14)	15 (21)	62 (16)	
Disease status pre-HCT	1 st CR/PR	26 (93)	60 (82)	318 (83)	0.4
	≥ 2 nd CR/PR	2 (7)	13 (18)	64 (17)	
HCT characteristics					
Donor age (years)	< 35	4 (14)	18 (25)	141 (37)	0.01
	≥ 35	22 (78.5)	51 (70)	233 (61)	
Donor sex (Recipient/Donor)	Male-female	3 (11)	17 (23)	58 (15)	0.6
	Female-male	8 (29)	23 (32)	103 (27)	
Donor Blood group	Major mismatch	5 (18)	18 (25)	84 (22)	0.7
Donor CMV serology	mismatch	7 (25)	19 (26)	163 (43)	0.008
HCT type	MSD	13 (46)	30 (41)	149 (39)	0.009
	MUD	6 (21)	22 (30)	171 (45)	
	Haplo/MMUD	7 (25)	16 (22)	46 (12)	
	Cord	2 (7)	4 (5)	8 (2)	
GVHD prophylaxis	No ATG/PTCy	15 (54)	33 (45)	181 (47)	0.8
	ATG/PTCy	11 (39)	31 (42)	171 (45)	
Conditioning	TBI	5 (18)	14 (19)	56 (15)	0.6
	Non-TBI	23 (82)	59 (81)	326 (85)	
CD34 dose (× 10 ⁶ /kg)	Median (IQR)	9.5 (6.0-10.7)	9.5 (6.8-12.8)	9.1 (6.9-11.7)	0.6
HCT outcomes					
CI of gr2-4 acute GVHD	at day+100	33%	34%	30.7%	0.7
CI of Moderate-severe chronic GVHD	at 1-year	25.5%	30.4%	30%	0.6
Relapse incidence	2-year	28.5%	24.7%	28%	0.8
Non-relapse mortality	2-year	35.7%	13.7%	16%	0.03
Cause of non-relapse mortality	RRT	4 (40%)	4 (40%)	26 (43%)	0.8
	Infection	4 (40%)	3 (30%)	19 (31%)	
	GVHD	2 (20%)	3 (30%)	16 (26%)	
Overall survival	months	19	103	65	0.04

ALL, acute lymphoblastic leukemia; AML, acute myeloid leukemia; MDS/MPN, myelodysplastic syndrome/myeloproliferative neoplasm; HCT, hematopoietic cell transplantation; CR, complete remission; PR, partial remission; CMV, cytomegalovirus; MSD, matched sibling donor; MUD, matched unrelated donor; MMUD, mismatched unrelated donor; ATG, anti-thymocyte globulin; PTCy, post-transplant cyclophosphamide; TBI, total body irradiation; IQR, interquartile range; CI, cumulative incidence; GVHD, graft versus host disease; RRT, regimen related toxicity

most typical indication for HCT was acute myeloid leukemia (46%), followed by myelodysplastic syndrome/myeloproliferative neoplasm (25%). Most HCTs were done for disease in first remission (84%). Most transplants were MSD (40%) and MUD-HCT (41%). A comparison of baseline characteristics of the patients across the three racial subgroups is summarised in **Table 1**. There was a lower proportion of older recipients (≥ 60 years of age) among Asians than among Whites (SA 21%, EA/SEA 14%, W 34%, $p=0.001$). The pro-

portion of older donors (≥ 30 years of age) was higher among Asians compared to Whites (SA 78.5%, EA/SEA 70%, W 61%, $p=0.01$). The three groups were comparable in terms of the proportion of recipient and donor sex, and performance status (Eastern Cooperative Oncology Group score ≥ 2). The proportion of patients with HCT-CI ≥ 3 was significantly higher in SA (SA 50%, EA/SEA 37%, W 31%, $p=0.03$). The proportion of patients with obesity (BMI ≥ 30 kg/m²) was significantly higher in SA (SA 29%, EA/SEA 5%, W 19%,

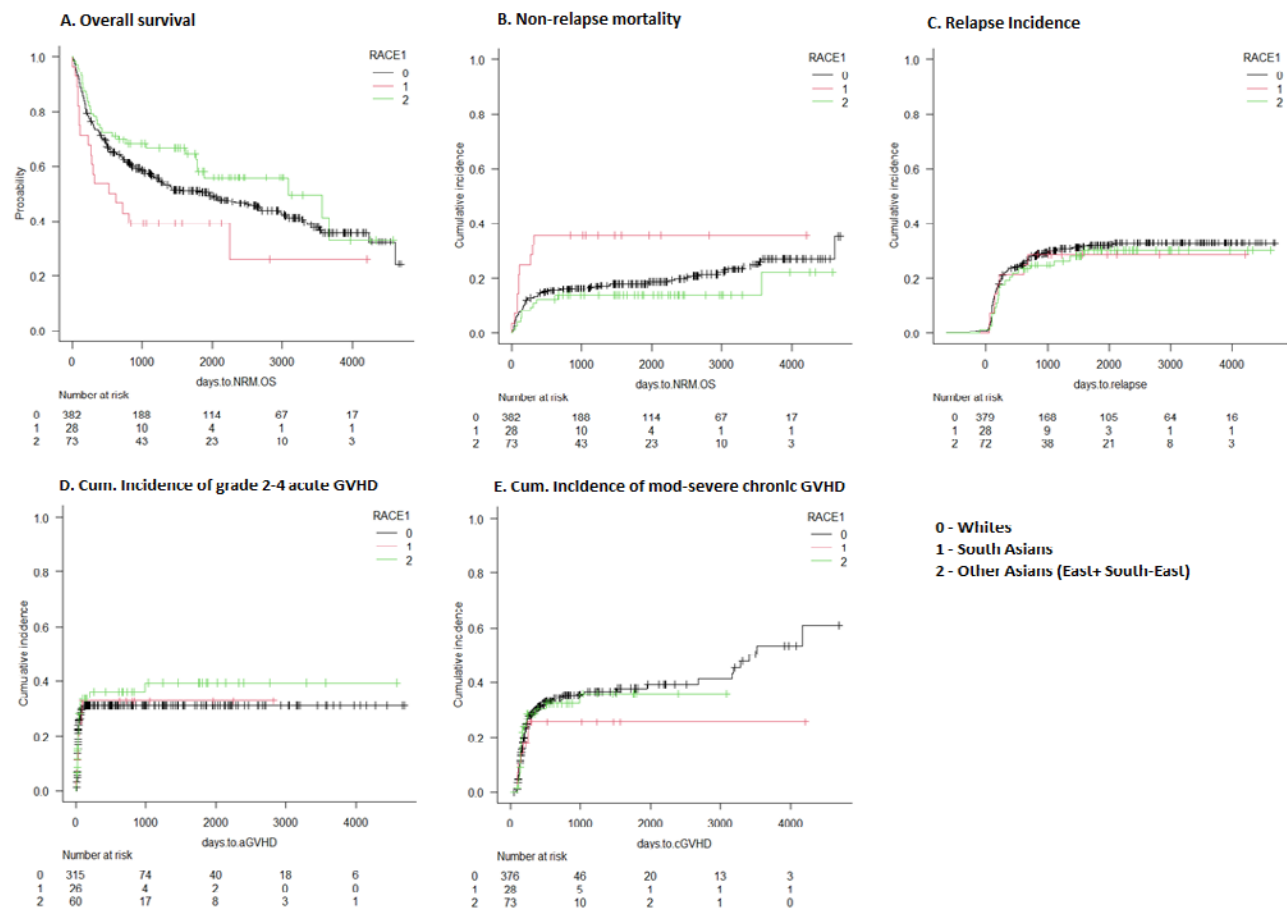


Figure 1. Overall survival, non-relapse mortality, relapse incidence and cumulative incidence of acute and chronic GVHD by race (0-Whites, 1-South Asian, 2-Other Asians)

$p=0.005$). There were fewer CMV mismatches among the Asians (SA 25%, EA/SEA 26%, W 43%, $p=0.008$). There was a lower proportion of MUD-HCT (SA 21%, EA/SEA 30%, W 45%) and a higher proportion of mismatched unrelated donor (MMUD)/haplo-HCT (SA 25%, EA/SEA 22%, W 12%) in the Asians ($p=0.009$). There was no difference in the proportion of patients receiving antithymocyte globulin (ATG)/post-transplant cyclophosphamide as GVHD prophylaxis (SA 39%, EA/SEA 42%, W 45%, $p=0.8$). There was no difference in the conditioning type (TBI or Busulfan-based) or median CD34 cell dose infused.

The median OS was significantly shorter in SA (SA 19, EA/SEA 103, W 65 months, $p=0.04$) (**Figure 1A**). The 2-year NRM was highest in SA (SA 35.7%, EA/SEA 13.7%, W 16%, $p=0.03$) (**Figure 1B**). There was no significant difference in the cause of death attributed to infections, regimen-related toxicity, and GVHD in the three groups. The 2-year RI was also not significantly different (SA 28.5%, EA/SEA 24.7%, W 28%, $p=0.8$) (**Figure 1C**). The cumulative incidence of grade 2-4 acute and moderate-severe chronic GVHD was not significantly different ($p=0.7$ & 0.6) (**Figure 1D**

Table 2. Multivariable analysis of factors affecting non-relapse mortality

Factor	Hazard ratio	p-value
Age $\geq$ 60 years	1.17 (0.66-2.05)	0.6
Obesity	0.87 (0.49-1.53)	0.62
Comorbidity index $\geq$ 3	1.14 (0.66-1.97)	0.64
CMV mismatch	1.10 (0.65-1.88)	0.72
Donor age $\geq$ 35 years	1.28 (0.63-2.60)	0.5
MSD	0.59 (0.24-1.49)	0.26
MUD	0.78 (0.37-1.64)	0.51
Haplo/MMUD	1.0	
South Asian	2.1 (1.11-4.17)	0.02
East/Southeast Asian	0.69 (0.36-1.30)	0.25
White	1.0	

CMV, cytomegalovirus; MSD, matched sibling donor; MUD, matched unrelated donor; MMUD, mismatched unrelated donor

and 1E). Upon multivariable analysis of the factors identified as significant in the univariate analysis, only race was found to be a significant factor affecting non-relapse mortality (**Table 2**). The hazard ratio for NRM was 2.1 (1.11-4.17) for South Asians ($p=0.02$) and 0.69 (0.36-1.30) for Southeast Asians ($p=0.25$).

Table 3. Comparison of studies reporting outcomes by race

Study (author, year, center)	Racial subgroups	Mortality Hazard ratio (95% CI)	p-value	Survival Hazard ratio (95% CI)	p-value
Mielcarek et al. ¹⁶ 2005 Fred Hutchinson Cancer Research Center	White Black Asian Hispanic Native American	1.0 1.65 (1.21-2.25) 0.62 (0.39-0.97) 0.98 (0.76-1.27) 0.92 (0.54-1.56)	< 0.05		
Baker et al. ⁴ 2009 Center for International Bone Marrow Transplant Registry	White African-American Asian Hispanic	1.0 1.56 (1.34-1.83) 0.99 (0.75-1.32) 1.30 (1.11-1.51)	< 0.01 NS < 0.01	1.0 1.47 (1.29-1.68) 0.96 (0.76-1.20) 1.15 (1.01-1.30)	< 0.01 NS NS
Morishima et al. ⁵ 2022 International Histocompatibility Working Group	White Black Japanese US Asian Hispanic	1.0 1.76 (1.39-2.23) 0.64 (0.57-0.73) 0.93 (0.73-1.19) 1.01 (0.80-1.28)	< 0.01 < 0.01 0.58 0.92		
Our study	White South Asian East/Southeast Asian	1.0 2.1 (1.11-4.17) 0.69 (0.36-1.30)	0.02 0.25	1.0 1.59 (0.98-2.58) 0.77 (0.53-1.11)	0.05 0.1

CI, confidence interval; NS, not significant

Discussion

Our study shows that in patients older than 45 years, South Asians have higher mortality, and other Asians may have lower mortality after MAC-HCT. The high NRM is probably due to differences in comorbidities, with a higher proportion of South Asians having HCT-CI ≥ 3 . South Asians were more likely to be obese as per the World Health Organization's definition. However, neither the comorbidity index nor obesity was identified as a risk factor affecting NRM on multivariable analysis. The high NRM with MAC regimens in South Asians has been demonstrated in studies from India, where RIC regimens are preferred in patients aged ≥ 45 years. In one study, the MAC regimen was associated with higher 100 day (18.4 vs 6%) and 1-year NRM (52.6 vs 20.9%) compared to reduced intensity chemotherapy (fludarabine/melphalan)¹⁰. British Columbia has a significant Asian population, with ~65.6% Whites, ~9.6% South Asians, and 18.6% East/Southeast Asians¹⁴. Its publicly funded healthcare system ensures equitable healthcare services and prescription medication access. The proportion of patients undergoing myeloablative conditioning was representative of the provincial population. Since we did not have data on the total number of patients eligible for HCT, it is difficult to determine if there was any racial disparity in the stem cell utilization rates. However, some centres in the US have reported selection bias in HCT and barriers to HCT in minority and low-income patients¹⁵. This could not have been the cause in our study, as the median income of Asians, including South Asians, was higher than the median national income¹⁶.

The impact of race as a determinant for outcomes following HCT has been a field of interest for decades.

Early studies showed a higher mortality among the US Black population, driven by a higher relapse and GVHD¹⁷. This was thought to be related to unidentified immunological or socio-cultural parameters. Socio-economic factors were ruled out as a cause for inferior outcomes in Black patients in a subsequent study⁴. This study attributed the inferior outcomes in Black patients to pharmacogenomic or unmeasured comorbidities.

A recent study showed survival was superior for Japanese, intermediate for U.S. Asian, White, and Hispanic, and lowest for Black patients, with optimal matching for donor and human leukocyte antigen (HLA) characteristics⁵ (Table 3). The reasons for lower mortality in Japanese and US Asians and higher mortality in Blacks were attributed to the genetic conservation of HLA haplotypes in Japanese patients and donors compared to diverse haplotypes in other races. Another recent CIBMTR study showed no difference in outcomes by race or poverty in those surviving ≥ 1 year after HCT⁶. As our study shows, this could be attributed to higher mortality in the first year after HCT. These studies are limited by the underrepresentation of South Asians or the inclusion of patients of all age groups. Our study is limited by its retrospective nature and the relatively limited number of South Asian patients.

Our study confirms that South Asians aged ≥ 45 have worse survival after MAC-HCT. Supportive care in a publicly funded universal healthcare setting did not overcome the differences in the outcomes. Future studies should prospectively focus on the combined effect of comorbidities, frailty, and pharmacogenetics as a cause for this racial disparity in HCT outcomes.

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Author Contributions

SM, SN, YAM, TJN, and DL conceived and wrote the study; SM and DL analyzed the data and wrote the first draft of the manuscript. All authors contributed to patient care and manuscript writing.

Conflicts of Interest

The authors declare no conflict of interest. Disclosure forms provided by the authors are available on the website.

DL is one of the editors of Blood Cell Therapy. He was not involved in the editorial evaluation or decision to accept this article for publication.

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