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Inferior Access to Allogeneic Transplant in Disadvantaged Populations: A CIBMTR Analysis

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Abstract

Allogeneic hematopoietic cell transplant (AlloHCT) is offered in a limited number of medical centers, and is associated with significant direct and indirect costs. The degree to which social and geographic barriers reduce access to AlloHCT is unknown. Data from the Surveillance, Epidemiology and End Results Program (SEER) and the Center for International Blood and Marrow Transplant Research (CIBMTR) were integrated to determine the rate of unrelated donor (URD) AlloHCT for acute myelogenous leukemia (AML), acute lymphoblastic leukemia (ALL), and myelodysplastic syndrome (MDS) performed between 2000–2010, in the 612 counties covered by SEER. The total incidence of AML, ALL, and MDS was determined using SEER, and the number of AlloHCTs performed in the same time period and geographic area were determined using the CIBMTR database. We then determined which sociodemographic attributes influenced transplant rate (rural/urban status, median family size, percent residents below the poverty line, and percent minority race). In the entire cohort, higher levels of poverty were associated with lower transplant rates (Estimated Rate Ratio, ERR, 0.86 for 10% increase in percentage of people below poverty line, $p < 0.01$), while rural location was not (ERR 0.87, $p = 0.11$). Thus, patients from areas with higher poverty rates diagnosed with ALL, AML, and MDS are less likely to receive URD AlloHCT compared to patients from wealthier counties. There is need to understand better the reasons for this disparity and encourage policy and advocacy efforts to improve access to medical care.

Keywords

Access to transplant; health services research; allogeneic transplant

Introduction:

For many patients with hematologic malignancies or non-malignant diseases, AlloHCT is the preferred treatment option. Many factors influence whether a patient eligible for transplant will go on to receive a transplant. Patients need to have a disease status that

renders them eligible to receive a transplant, have a suitable performance status and organ function, and have an available donor. In addition, many sociodemographic variables such as insurance coverage might impair access to AlloHCT [1]. A literature review conducted by Majhail et al in 2000 summarized the factors that might influence access to transplant, and broadly categorized them into five groups: donor availability, social, economic, provider, and health care system[2]. The degree to which these factors, particularly socioeconomic factors, might influence access to transplant is unknown.

One small study examining access to stem cell transplantation in Canada found rural patients were somewhat less likely to receive an AutoHCT compared to urban patients, although this was not statistically significant possibly due to small numbers[3]. One recent publication found that the majority of Americans were located within reasonable driving distance of a stem cell transplant center (78.6% within a 90 minute drive, 94.7% within a 180 minute drive)[4]. While this study might suggest physical geography is not a significant barrier to transplant, this study did not attempt to compare transplant rates between rural and urban Americans, or how transplant rates varied by other sociodemographic variables. An abstract presented at the most recent TCT meeting found that residents of Virginia diagnosed with AML were less likely to receive a transplant if they were from regions with higher numbers of African Americans[5]. In solid organ transplantation, multiple prior studies have shown inferior access to transplant in patients living in rural areas, or among patients of disadvantaged sociodemographic status[6–8]. This research has not been replicated in AlloHCT.

Multiple prior studies have shown that patients from disadvantaged areas might have inferior outcomes after AlloHCT. Loberiza et al compared outcomes of patients in the CIBMTR database by different sociodemographic attributes (income, rural/urban status) and found no difference in overall survival.[9] In contrast, Khera et al found that patients residing further away from a transplant centre who received a non-myeloablative transplant might have inferior outcomes.[10] However, neither of these studies attempted to compare access to transplant in different sociodemographic groups.

We sought to understand how the rate of AlloHCT varied by rural/urban status, socioeconomic status, and racial composition of the county of residence of the patient at the time of diagnosis. As data on the location of primary residence were lacking for patients receiving related donor AlloHCT, we focused on unrelated donor (URD) AlloHCT as a potential surrogate for access to transplant overall.

Methods:

This study integrated data from the Center for International Blood and Marrow Transplant Research (CIBMTR), and the Surveillance Epidemiology and End Results program (SEER), maintained by the National Cancer Institute (NCI)[11,12]. The Center for International Blood & Marrow Transplant Research (CIBMTR), is a research affiliation between the National Marrow Donor Program(NMDP)/Be The Match and the Medical College of Wisconsin (MCW). The CIBMTR comprises a voluntary working group of more than 450 transplantation centers worldwide that contribute detailed data on consecutive allogeneic and

autologous hematopoietic cell transplantation to a Statistical Center at the Medical College of Wisconsin in Milwaukee and the NMDP Coordinating Center in Minneapolis. Participating centers are required to report all transplants consecutively. Mandatory reporting of data on all transplant recipients to the CIBMTR results in universal capture of transplant activity in the United States[12]. SEER maintains a population based database of cancer incidence and survival, covering 612 counties in 15 states, representing approximately 28% of the United States population. In the SEER coverage area, all new diagnoses of malignancy are required to be reported, resulting in a comprehensive, population based database of cancer incidence. The three most common malignant indications for AlloHCT are acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), and myelodysplastic syndrome (MDS)[11]. Data on the incidence of AML, ALL, and MDS were abstracted from SEER, and data on transplant activity were abstracted from CIBMTR.

All patients with a diagnosis of ALL, AML, or MDS between January 1, 2000 and December 31, 2009 were included in this study. Date of diagnosis, rather than date of transplant, was used to determine eligibility for inclusion in the cohort, as date of transplant was not available in the SEER dataset, while date of diagnosis was included in both databases. Since during the study period AlloHCT was uncommon among patients over age 65, the analysis was restricted to patients under the age of 65.9

The primary variable through which the patient residence is captured in the CIBMTR database is ZIP code. ZIP code was captured on a majority of patients undergoing unrelated donor (URD) AlloHCT, but ZIP code data were substantially incomplete for patients undergoing related donor AlloHCT, therefore this analysis was restricted to recipients of URD AlloHCT. The indications for related donor and unrelated donor transplant are similar and we hoped to use access to unrelated AlloHCT as a surrogate for access to all AlloHCT in general. Potential causes for differential access to related or unrelated transplant are family size and race/ ethnicity. To account for this, the average family size of each county was captured and incorporated in the analysis. A sensitivity analysis restricted to White patients was completed to ensure that any difference in access seen reflected barriers to AlloHCT other than differences in donor availability among minority populations.

For each of the 612 counties reporting data to SEER, the number of new incident cases of AML, ALL, and MDS between January 1, 2000 and December 31, 2009 was retrieved from SEER. From CIBMTR, the number of URD AlloHCTs performed for ALL, AML, and MDS with a date of diagnosis over the same time period and geographic area was obtained. Date of diagnosis was used as the inclusion criteria in both cohorts, and not date of transplant, to ensure that the transplant activity corresponded with the SEER data. Thus, for each of the 612 counties covered, a transplant rate was calculated (number of transplants performed divided by the number of new diagnoses). Next, a number of descriptive attributes were chosen to describe the sociodemographic makeup of that county. First, we determined the percent of that county population with a median income below the poverty line in 2000, from the United States Census conducted in 2000[13]. Race was included by examining the percent of the county population in the year 2000 belonging to racial groups other than White alone (including Black, American Indian/Alaska Native, Asian/Pacific Islander, and Hispanic). The Rural-Urban Continuum Code (RUCC) was used to categorize counties into

9 groups based on population size and proximity to a major urban center[14]. These nine groups were then collapsed into three groups: metropolitan (>50,000 residents), micropolitan (20,000 – 50,000 residents), or rural (< 20,000 residents).

The rate of AlloHCT in the 612 counties covered by SEER was compared using univariate and multivariate analysis. The expected rate ratio was calculated for all county attributes (a ratio comparing the transplant rate for each attribute against a baseline group). Poisson regression was used to compare the rate of transplant in rural and urban counties after adjusting for other possibly significant covariates. Racial/ethnic composition of the county, poverty rate and average family size were examined in the model. A backward elimination model selection procedure was employed to identify statistically significant covariates to be added into the model.

Generalized linear mixed model framework enabled us to treat county as a random effect with specific correlation structure where correlation between two observations depends on the distance between them. The Euclidean distance between counties is computed based on the coordinates (latitude and longitude) of the center of each county.

The primary analysis cohort consisted of all patients with ALL, AML, and MDS. In addition, there were three pre-planned sensitivity analyses. First, as mentioned previously, an analysis restricting both the number of diagnoses and transplants to White patients was done, to eliminate any bias introduced by differential availability of unrelated donors among different racial groups. Next, an analysis was done restricting the study population to only AML, to provide for a more homogenous study population. Finally, an analysis was done restricting the population to only pediatric patients (age < 18 at time of diagnosis) with ALL, to examine any differences in access among pediatric patients.

A statistical significance (alpha) level of 0.05 was used throughout. SAS statistical software (SAS Institute, Cary, NC) is used to perform all statistical analyses.

Results:

There were 30,468 new incident diagnoses of ALL, AML, and MDS in the SEER database. 3147 patients were identified in the CIBMTR dataset that met inclusion criteria (Table 1). The estimated ZIP code completeness was 75%. The overall rate of URD AlloHCT was 10.3% in patients under age 65 diagnosed with ALL, AML, or MDS.

In univariate analysis, the only significant predictor of transplant rate was the percentage of residents below the poverty line (Table 2) (Estimated rate ratio, ERR, 0.84 for each 10% increase, p = 0.0007). There was no significant difference in transplant rate between rural, micropolitan, and metropolitan counties (p = 0.07). Similarly, there was no difference in transplant rate with variation in the percentage of minority residents (ERR 0.98 for each 1 point increase in percentage of minority residents, p = 0.09). Finally, the median family size of the county was also not associated with a difference in transplant rate (ERR 0.77 for each person increase, p=0.10).

Our final multivariable model included the percentage of the county population with an income below the poverty level because it was significant in the univariate analysis. Rural/urban status was forced into the model as it was one of the factors of primary interest. Higher percentage of individuals below poverty remained significantly associated with lower transplant rates (ERR 0.86 for each 10% increase, p = 0.003), while location of residence was not (p = 0.24) (Table 3).

Results of the sensitivity analysis restricted to AML patients only were similar to the entire cohort (Table 4). In multivariate analysis, the most important predictors of low transplant rates were the percentage of county residents below the poverty line, and the geographic location of the country (rural versus urban). These results were replicated in the analysis restricted to White Americans, among which we found that rural location and high levels of poverty were associated with lower transplant rates. Results were different in the pediatric ALL cohort, with neither rural/urban location nor poverty rate being associated with transplant rate. In all multivariable models in the sensitivity cohorts, minority status and family size were not significant.

Finally, to ensure that URD AlloHCT was a reasonable surrogate for AlloHCT in general, we compared recipients of related and unrelated donor AlloHCT in the CIBMTR dataset. We found no significant differences in characteristics reviewed (disease, disease status at time of transplant, year of transplant, disease risk status, and patient age).

Discussion:

Several previous studies have attempted to compare outcomes following alloHCT based on sociodemographic factors, but to our knowledge, this is the first study aiming to explore sociodemographic factors influencing access to URD alloHCT. Given the important role of AlloHCT in the treatment of hematologic malignancies (particularly AML and MDS), it is essential that all eligible patients have access to AlloHCT, regardless of location of primary residence, income, or racial group. Studies examining outcomes following AlloHCT are restricted to patients with sufficient resources to proceed to transplant, and might not be representative. Thus, while research studying outcomes following AlloHCT in disadvantaged groups is important, it is equally important to ensure that patients in these groups actually have access to transplant.

In this study, we found that patients diagnosed with AML, ALL, and MDS were significantly less likely to receive URD AlloHCT as a part of their treatment if they lived in areas with higher poverty rates. The lower rates of transplant among patients residing in counties with higher poverty rates were seen in the main cohort, and in all sensitivity cohorts except pediatric ALL. The impact of other sociodemographic variables was less consistent. While rural location was associated with lower rates of transplant in some cohorts (AML diagnoses), it was not significant in any multivariable models. Family size and minority status were not associated with lower rates of transplant in any models. Thus, the most important predictor of access to URD AlloHCT was the poverty rate in the county of residence.

The lack of a significant difference in transplant rates for pediatric patients in areas with higher poverty rates is an interesting finding. It is possible that this is due to differences in statistical power, due to smaller numbers in that subgroup. Alternatively, barriers to transplant (insurance status, presence of a caregiver, clinical trial rates) are different in the pediatric setting compared to the adult setting. This is an area that deserves more study.

There are several reasons why patients living in areas with higher rates of poverty might have lower rates of transplant. Firstly, although Medicaid coverage is available to some families below the poverty line, Medicaid does not cover all direct and indirect costs of AlloHCT. In addition, areas with higher rates of residents below the poverty line also have higher rates of poor residents but with income levels above the threshold required for Medicaid. Finally, there are a number of ancillary costs associated with transplant that are not covered by insurance that might be a barrier to transplant.

This study has several strengths and weaknesses. It is the only study to date reviewing access to AlloHCT across different sociodemographic populations, using two well established population based registries (SEER and CIBMTR). Our results were consistent with previous studies in other fields, showing that poverty rate has a clear impact on transplant rate.

This study was restricted to unrelated donor transplant only. While we believe that this is a reasonable surrogate for transplant activity in general, this hypothesis was not tested with this study. There are several reasons why rates of URD AlloHCT might differ from overall transplant rates, primarily due to donor availability. We attempted to address this by including average family size in the model. In all transplant related variables reviewed in the CIBMTR dataset, there were no other differences seen between the recipients of related and unrelated donor AlloHCT. Finally, due to lower rates of available matched unrelated donors in other racial groups[1], we attempted to address differences in availability of matched unrelated donors through the sensitivity analysis restricted to White Americans. The primary conclusion of our study (lower transplant rates in areas with more poverty) was upheld in this subgroup analysis. Thus, we believe that access to URD AlloHCT is a reasonable surrogate for access to AlloHCT in general.

In addition, there was a significant amount of missing ZIP code data (25%). While we believe this data to be missing at random, this is a weakness of our study. There was no difference in baseline transplant variables between patients with available and missing ZIP code data, suggesting no significant bias as a result of this missing data.

It is a notable finding that only 10% of patients diagnosed with AML, ALL, and MDS went on to receive an allogeneic transplant from an unrelated donor. Unrelated donor transplant was the most common donor source throughout this study period, accounting for approximately 40% of all allogeneic transplants performed.[12] Given that large donor versus no donor studies done in that time period showed that the majority of patients with AML would benefit from allogeneic transplant,[15] this transplant rate seems low. Reasons for the low overall rate of transplant beyond sociodemographic barriers, including referring physician education and other systematic barriers to transplant should be studied.

We attempted to model the number of patients who might be excluded from transplant due to the aforementioned barriers. Firstly, we assumed that the differences in transplant rate seen in URD AlloHCT were representative of all AlloHCT, regardless of donor source. Next, we modeled a scenario in which poverty as a barrier to transplant was eliminated (setting the ERR for poverty to 1.0). Based on transplant activity reported to the CIBMTR, the total number of transplants would increase by 2500 patients per year (an increase of approximately 30%).

In summary, we found that patients from areas with higher levels of poverty diagnosed with ALL, AML, and MDS were less likely to receive an URD AlloHCT. This effect was significant even when adjusting for other potential barriers, such as rural residency or racial origin. Modeling done using these results suggests that approximately 2500 patients annually do not receive a transplant due to poverty. Given the significant number of patients annually who are potentially being excluded from transplant due to socioeconomic status, attempting to improve access to transplant in these populations should be a high priority for policy makers. Further studies are required to advance our understanding which specific factors drive lower access to transplant in areas with lower socioeconomic status, and to determine which interventions might be successful in reducing this significant inequity.

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Highlights:

- AML, ALL, and MDS patients from areas with more poverty had lower rates of AlloSCT
- These results were confirmed by multiple sensitivity analyses
- Family size, minority status, and rural residence were less important than poverty rate
- 2500 additional patients/year would undergo AlloSCT if poverty was not a barrier

Table 1a:

Transplant Rate by County Attributes

Category	Mean Unrelated Donor Transplant Rate
Rural / Urban	
Metropolitan (County > 50,000 residents)	8.77%
Micropolitan (County 20,000 – 50,000 residents)	8.93%
Rural (County < 20,000 residents)	7.54%
Poverty Rate	
Highest Quartile (most poverty) (22.5% – 40.3% residents below the poverty line)	7.44%
50–75% quartile (17.5% – 22.5% residents below the poverty line)	7.39%
25–50% quartile (12.7% – 17.5% residents below the poverty line)	10.16%
Lowest Quartile (least poverty) (3.2% −12.7% residents below the poverty line)	11.73%
Highest Quartile (most minorities) (34.3% – 84.9% minority residents)	7.17%
50–75% quartile (15.3% – 34.3% minority residents)	8.33%
25–50% quartile (5.3% – 15.3% minority residents)	8.81%
Lowest Quartile (least minorities) (1.1% – 5.3% minority residents)	12.37%
Median Family Size	
Highest Quartile (largest families) (Median family size 3.15 – 3.88 persons)	7.84%
50–75% quartile (Median family size 3.03 – 3.15 persons)	8.96%
25–50% quartile (Median family size 2.93 – 3.03 persons)	8.16%
Lowest Quartile (smallest families) (Median family size 2.49 – 2.93 persons)	11.77%

Table 1b:

Descriptive Statistics for Continuous Variables:

Category	Median (range)
Poverty Rate	17.5 (3.2 – 40.3)% residents below the poverty line
Percent Minority	15.3 (1.1 – 84.9)% minority residents
Median Family Size	3.03 (2.49 – 3.88) persons

Table 2:

Univariate Results, Entire Cohort

Category	Expected Rate Ratio (95%CI)	p-value
County size		
Metropolitan (county > 50,000 residents)	1.00	0.07*
Micropolitan (county > 20,000 residents)	0.99 (0.81–1.22)	0.96
Rural (county < 20,000 residents)	0.82 (0.68–0.97)	0.0225
Percent below poverty (continuous variable)		
10% Increase	0.84 (0.76–0.93)	0.0007
Percent minority (continuous variable)		
1% Increase	0.997 (0.94–1.001)	0.09
Median family size (continuous variable)		
1 Person Increase	0.77 (0.55–1.06)	0.10

* Overall p-value (2 degree- o- freedom test)

Table 3:

Multivariate Results, Entire Cohort

Category	Expected Rate Ratio	p-value
County size		
Metropolitan (county > 50,000 residents)	1.00	0.24*
Micropolitan (county > 20,000 residents)	1.03 (0.83–1.26)	0.80
Rural (county < 20,000 residents)	0.87 (0.72–1.03)	0.11
Percent below poverty (continuous variable)		
10% Increase	0.86 (0.77–0.95)	0.003

*Overall p-value (2 degree- o- freedom test)

Table 4:

Univariate Sensitivity Analyses

County attribute	Status	Acute Myeloid Leukemia		Pediatric Acute Lymphoblastic Leukemia		White Residents Only	
		Expected Rate	p-value	Expected Rate	p-value	Expected Rate	p-value
County size	Metropolitan	1.00	0.01 *	1.00	0.25 *	1.00	0.04 *
	Micropolitan	0.91	0.51	0.73	0.38	1.03	0.80
	Rural	0.71	0.003	0.70	0.13	0.79	0.80
Percentage below poverty level	10% increase	0.79	0.0002	0.80	0.11	0.85	0.004
Percent minority	1 % increase	0.997	0.21	0.998	0.73	1.002	0.41
family size	For each person increase	0.995	0.98	1.45	0.26	0.82	0.27

* Overall p-value (2 degree- o- freedom test)