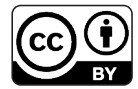


ORIGINAL ARTICLE

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HEMATOPOIETIC CELL TRANSPLANTATION IN BRAZIL: A NATIONAL BENCHMARKING STUDY FOCUSED ON THE FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY (FACT) PERFORMANCE INDICATORS

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ABSTRACT

Systematic evaluation of hematopoietic cell transplantation (HCT) outcomes is essential to improve clinical practice and meet international quality standards. In Brazil, the partnership between the Brazilian Society of Cellular Therapy and Bone Marrow Transplantation (SBTMO) and the Center for International Blood and Marrow Transplant Research (CIBMTR) has advanced national data reporting and benchmarking through the Hematopoietic Cell Transplantation Brazilian Registry (HCTBR). This study reports outcomes from 11,210 first HCTs (5,984 allogeneic; 5,226 autologous) performed between 2012 and 2023 across 44 Brazilian centers.

Median recipient age was 29 years for allogeneic and 53 years for autologous transplants. Acute leukemias predominated among allogeneic cases, while multiple myeloma was the most common indication for autologous HCT. Two-year overall survival was 82.0% for autologous and 59.8% for allogeneic transplants, with variation by donor type (matched related 61.8%, mismatched related 54.0%, unrelated 63.3%). Two-year non-relapse mortality was 8.0% and 21.6% for autologous and allogeneic transplants, respectively. The cumulative incidence of grade II–IV acute graft-versus-host disease (GVHD) at two years was 29.9%, with chronic GVHD incidence of 29.5%. Two-year relapse incidence was 24.1% for allogeneic and 25.8% for autologous HCT.

Despite challenges within the Brazilian healthcare system, these outcomes align with international registry data. Adequate data completeness supports the robustness of these findings. Our results highlight the quality of Brazilian transplant programs and underscore the value of standardized outcome monitoring to foster continuous improvement. Strengthening center participation, follow-up, and data management remains critical to maintaining registry quality and enhancing patient care.

Keywords: Hematopoietic Stem Cell Transplantation. Data management. Brazil.

INTRODUCTION

Reliable and systematic evaluation of hematopoietic cell transplantation (HCT) outcomes is crucial for improving clinical practices and ensuring compliance with international quality standards. The Center for International Blood and Marrow Transplant Research (CIBMTR), a research collaboration between the Medical College of Wisconsin and the NMDP (formerly National Marrow Donor Program), captures activity and outcomes of HCTs both in the USA and worldwide. Since 1989, Brazilian centers have contributed to this global data collection, but in 2016, a significant development occurred: the Brazilian Cellular Therapy and Bone Marrow Transplant Society (SBTMO) partnered with the CIBMTR to implement a program for training professionals in data collection. This partnership significantly increased the number of Brazilian centers reporting to the CIBMTR¹, which, in turn, facilitated the development of the Hematopoietic Cell Transplantation Brazilian Registry (HCTBR).² This registry consolidates data from Brazilian centers and returns it to the SBTMO for analysis. As a result, the HCT activity from Brazilian centers is now published annually on the SBTMO website, serving as a valuable resource for the transplant community and allowing for continuous assessment of clinical outcomes and practices across the country.³⁻⁷

The Foundation for the Accreditation of Cellular Therapy (FACT) establishes rigorous international standards for quality control and outcomes measurement in cellular therapies. Centers seeking FACT accreditation must evaluate key outcome metrics, including time to neutrophil and platelet engraftment, overall and treatment-related mortality, as well as the incidence and severity of acute and chronic graft-versus-host disease (GVHD).⁸ These outcome measures, along with the Brazilian registry data, serve as important benchmarks for clinical performance, enabling Brazilian centers to align with global best practices and facilitating international comparisons. This continuous monitoring and reporting of outcomes is vital for ensuring that Brazilian HCT centers maintain high standards of care and contribute to the global effort of improving cellular therapy outcomes.

OBJECTIVE

The objective of this study is to describe hematopoietic cell transplantation (HCT) outcomes in Brazil, with an emphasis on performance indicators required by FACT standards. By presenting a comprehensive national overview, this study aims to assist Brazilian centers in evaluating their outcomes, benchmarking their performance against national data, and reinforcing initiatives toward achieving and maintaining FACT accreditation.

METHODS

Data Sources

Brazilian transplant centers report their data to the CIBMTR, using the electronic FormsNet3 platform. That process is protected by double authentication entry requirements for all system users. The compiled, standardized and codified data returns to SBTMO through the Data Back to Centers (DBtC) tool, enabling the analysis of HCT outcomes throughout the country.

Selection

Data from 11,210 first hematopoietic cell transplants (HCTs) performed between 2012 and 2023 (comprising 5,226 autologous and 5,984 allogeneic transplants) were extracted from the CIBMTR portal using the Data Back to Centers (DBtC) tool. Data were obtained from 44 Brazilian centers that reported their HCT activity to the CIBMTR.

There were considered complete those patients with information about type of transplant, diagnosis and graft source.

The spreadsheet was imported into Power BI Desktop (PBI). Functions were updated to count the number of transplants performed and the number of participating centers.

Definitions and Outcomes

Patients were classified as pediatric (0-17 years of age) and adults (≥ 18 years of age).

Allogeneic transplants were categorized as matched related donor, mismatched related donor (including haploidentical and related donors with one mismatch), and unrelated donor.

Grafts were classified as bone marrow (BM), peripheral blood stem cells (PBSC) and umbilical cord blood (UCB).

Non-Relapse Mortality (NRM)

For the analysis of non-relapse mortality (NRM), cumulative incidence analysis with competing risks was performed, considering relapse as the competing event.⁹ Cases without information on relapse status (Yes/No) or lacking the date of relapse were excluded.

Acute Graft-versus-Host Disease (aGVHD)

The cumulative incidence of acute graft-versus-host disease (aGVHD) grade II–IV and grade III–IV was evaluated, considering death without aGVHD as a competing risk. Exclusion criteria were: transplants performed before 2017 (since information regarding the date of aGVHD diagnosis became available only from 2017 onward), cases without information on relapse status or lacking the date of relapse, absence of data on aGVHD occurrence, missing information on the date of aGVHD diagnosis, missing grading of aGVHD, and erroneous records in which the reported date of aGVHD diagnosis.

Chronic Graft-versus-Host Disease (cGVHD) and Relapse

For the analyses of chronic graft-versus-host disease (cGVHD) and relapse, the completeness of follow-up was assessed.^{10,11} Centers achieving a completeness index greater or 80% were included in the respective analyses. Additionally, cases were excluded if they had missing information on the occurrence of the event (cGVHD or relapse), lacked a date for the event diagnosis, or exhibited implausible data entries.

Statistical analysis

Descriptive statistics were used to describe categorical data with number of cases and percentage, to numerical variables were used median and ranges. Overall survival was estimated by the Kaplan Meier method, and the log-rank test was used to compare survival between groups. Cumulative incidence functions were used to estimate the incidence of competing risk events. Graphics were generated by PBI and exported to Microsoft PowerPoint for

publication. Survival and competing risk analyses were performed using R Statistical Software (Version 4.2.1).

Ethical considerations

Ethics approval for utilization of the CIBMTR platform for the Brazilian Registry for research was obtained from the national Institutional Review Board (IRB) in 2019 (Conep CAAE: 65575317.5.1001.0071, principal investigator Dr. Nelson Hamerschlag).

RESULTS

A total of 11,210 first HCTs performed between 2012 and 2023 were analyzed, comprising 5,984 allogeneic and 5,226 autologous transplants. The median age at infusion was 29 years (IQR 12–47) for allogeneic and 53 years (IQR 36–62) for autologous recipients. Among allogeneic HCTs, 40.4% had an HLA-matched related donor, 29.8% had a mismatched related donor, and 29.7% had an unrelated donor. The most frequent diagnoses were acute leukemias (53.9%) in allogeneic transplants and multiple myeloma (52.5%) in autologous transplants. A detailed description of patient and transplant characteristics is provided in Table 1.

Overall Survival

Overall survival (OS) was estimated separately for autologous and allogeneic hematopoietic cell transplantation (HCT). For **autologous HCT**, the OS was 97.7% at 30 days, 96.0% at 100 days, 94.0% at 6 months, 88.9% at 1 year, and 82.0% at 2 years. For **allogeneic HCT**, the OS was 93.9% at 30 days, 84.9% at 100 days, 77.8% at 6 months, 68.5% at 1 year, and 59.8% at 2 years (Figure 1).

Among allogeneic transplants, the 2-year OS varied according to donor type: matched related donors (61.8%), mismatched related donors (including haploidentical, 54.0%), and unrelated donors (63.3%) (Figure 2).

Non-Relapse Mortality

Among the 11,210 transplants performed, 7,168 cases were eligible for analysis of non-relapse mortality (NRM) after excluding patients with missing data on relapse status or relapse date. Cumulative incidence analysis was performed, considering relapse as a competing event.

For autologous transplants, the cumulative incidence of NRM was 1.8% at 30 days, 3.1% at 100 days, 3.8% at 6 months, 5.7% at 1 year, and 8.0% at 2 years. For allogeneic transplants, NRM was 4.8% at 30 days, 11.1% at 100 days, 15.1% at 6 months, 18.8% at 1 year, and 21.6% at 2 years (Figure 3).

When stratifying allogeneic transplants by donor type, the cumulative incidence of NRM varied across groups. At 2 years, NRM was 16.3% for matched related donors, 28.1% for mismatched related donors, and 23.0% for unrelated donors (Figure 4).

Acute Graft-versus-Host Disease

Among the 5,984 allogeneic transplants, 2,719 were eligible for the analysis of acute graft-versus-host disease (aGVHD) after applying exclusion criteria. The cumulative incidence of grade II–IV and grade III–IV aGVHD was estimated using competing risk analysis, considering death without aGVHD as the competing event.

The overall incidence for aGVHD grade II–IV was 11.0% at 30 days, 23.6% at 100 days, 27.7% at 6 months, 29.3% at 1 year, and 29.9% at 2 years. The median time between transplant and aGVHD diagnosis was 37 days. When stratified by donor type, the cumulative incidence at 2 years was 24.6% for matched related donors, 33.7% for mismatched related donors, and 33.5% for unrelated donors (Figure 5).

For grade III–IV aGVHD, the overall cumulative incidence was 4.6% at 30 days, 8.3% at 100 days, 9.5% at 6 months, 10.2% at 1 year, and 10.4% at 2 years. At 2 years, the cumulative incidence of grade III–IV aGVHD by donor type was 8.5% for matched related donors, 10.6% for mismatched related donors, and 13.5% for unrelated donors (Figure 6).

Chronic Graft-versus-Host Disease (cGVHD)

The analysis of chronic graft-versus-host disease (cGVHD) was restricted to 2,918 allogeneic transplants from centers that achieved a completeness index (CIC) of at least 80%, after applying the exclusion criteria related to missing or implausible event data. The overall cumulative incidence of cGVHD was 13.4% at 6 months, 24.7% at 1 year, and 29.5% at 2 years post-transplant. When stratified by donor type, the 2-year cumulative incidence was 34.1% for matched related donors, 24.3% for mismatched

related donors, and 27.4% for unrelated donors (Figure 7).

Regarding moderate to severe cGVHD, the global cumulative incidence was 7.9% at 6 months, 14.3% at 1 year, and 17.3% at 2 years. At 2 years, the cumulative incidence by donor type was 20.8% for matched related donor, 13.7% for mismatched related donor, and 15.1% for unrelated donor (Figure 8).

Relapse

Among the 2,918 allogeneic transplants eligible for the relapse analysis—after excluding cases based on missing data and selecting centers with a completeness index (CIC) of $\geq 80\%$ —the cumulative incidence of relapse was 5.9% at 100 days, 12.7% at 6 months, 18.2% at 1 year, and 24.1% at 2 years. At the 2-year mark, the cumulative incidence of relapse by donor type was 27.7% in matched related donor transplants, 21.6% in mismatched related donor transplants, and 20.3% in unrelated donor transplants (Figure 9).

Among the 2,656 autologous transplants included in the relapse analysis—after applying the exclusion criteria and completeness filters—the cumulative incidence of relapse was 3.0% at 100 days, 7.6% at 6 months, 15.0% at 1 year, and 25.8% at 2 years (Figure 10).

DISCUSSION

Although not all transplant centers in Brazil are currently part of the HCTBR, this analysis is based on a robust multicenter cohort involving 44 institutions and over 11,000 hematopoietic cell transplants (HCT) performed between 2012 and 2023, demonstrating consistent clinical outcomes for both autologous and allogeneic transplants.

Despite the financial and infrastructural challenges of the Brazilian healthcare system, transplant outcomes reported here align with those observed in international literature. Overall survival, relapse, non-relapse mortality (NRM), and graft-versus-host disease (GVHD) rates were within expected ranges, as described by major global registries.^{12,13}

Incidence of acute and chronic GVHD reflected the diversity of donor types and conditioning regimens employed across centers. Relapse remained the leading cause of late mortality, particularly among

patients with high-risk disease, while NRM continued to impact outcomes in specific subgroups, such as older patients and those with alternative donors.^{14,15}

To ensure the robustness of long-term outcome analyses, particularly for chronic GVHD and relapse, data completeness was assessed using the completeness index, which confirmed adequate data capture in the majority of cases. This metric supports the reliability of survival estimates and strengthens comparisons with international registries.

These findings suggest that Brazilian transplant centers are achieving outcomes comparable to those reported by internationally accredited programs, such as those certified by FACT or JACIE¹⁶. This highlights the importance of ongoing efforts to standardize data collection, monitor quality indicators, and participate in benchmarking initiatives.

Finally, routine monitoring of transplant outcomes using standardized indicators is essential for improving both data quality and clinical care.

Continuous performance tracking, combined with comparisons to expected benchmarks, allows transplant programs to identify opportunities for improvement and implement targeted strategies to enhance patient outcomes.

CONCLUSION

The consolidation of the Brazilian transplant registry (HCTBR), through the partnership between the SBTMO and the CIBMTR, has enabled the generation of consistent national data on transplant outcomes. This advancement allows for the publication of results that serve as a benchmark for transplant centers across Brazil, fostering continuous improvements in data quality and patient care.

Nevertheless, key challenges persist. Strengthening the engagement of transplant centers in data reporting, improving long-term follow-up, and investing in the ongoing education of data managers are essential steps toward ensuring the continued quality and reliability of the registry.

TABLE 1. Baseline characteristics of patients undergoing first hematopoietic cell transplantation (HCT) in Brazil between 2012 and 2023.

	Allogeneic	Autologous
Total	5984	5226
Patient.Age.At.Infusion		
median(IQR)	29 (12,47.2)	53 (36,62)
0-17 years	2012 (33.6)	390 (7.5)
18-39 years	1852 (30.9)	1118 (21.4)
40-59 years	1527 (25.5)	2072 (39.6)
60 years or older	593 (9.9)	1646 (31.5)
Gender		
Female	2422 (42)	2202 (43.6)
Male	3351 (58)	2850 (56.4)
Donor		
Matched related donor	2420 (40.4)	-

Mismatch related donor	1786 (29.8)	-
Unrelated donor	1778 (29.7)	-
Diagnóstico		
Aplastic anemia	626 (10.5)	0 (0)
Myeloproliferative neoplasm (MPN)	149 (2.5)	0 (0)
Acute lymphoblastic leukemia (ALL)	1468 (24.5)	5 (0.1)
Acute myeloid leukemia (AML)	1693 (28.3)	67 (1.3)
Chronic myeloid leukemia (CML)	362 (6)	1 (0)
Hodgkin lymphoma (HL)	47 (0.8)	920 (17.6)
Non-Hodgkin lymphoma (NHL)	143 (2.4)	1064 (20.4)
Multiple myeloma (MM)	3 (0.1)	2740 (52.4)
Other non-malignant diseases	720 (12)	37 (0.7)
Other leucemias	152 (2.5)	2 (0)
Other malignant diseases	2 (0)	390 (7.5)
Myelodysplastic syndrome (MDS)	619 (10.3)	0 (0)
HCT-CI		
HCTCI 0	4157 (69.5)	3287 (62.9)
HCTCI 1-2	1217 (20.3)	1322 (25.3)
HCTCI ≥3	400 (6.7)	430 (8.2)
Unknown	210 (3.5)	187 (3.6)
Conditioning		
Myeloablative	4045 (67.6)	-
Non-myeloablative/Reduce intensity	1846 (30.8)	-
Unknown	93 (1.6)	
Product type		
Bone marrow	3241 (54.2)	86 (1.6)
PBSC	2627 (43.9)	5139 (98.3)
Cord blood	116 (1.9)	1 (0)
Performance Status		
90 ou 100%	4661 (77.9)	3984 (76.2)
<90%	1122 (18.8)	965 (18.5)
Unknown	201 (3.4)	277 (5.3)

FIGURE 1. Kaplan-Meier curves for overall survival following hematopoietic cell transplantation in Brazil between 2012 and 2023.

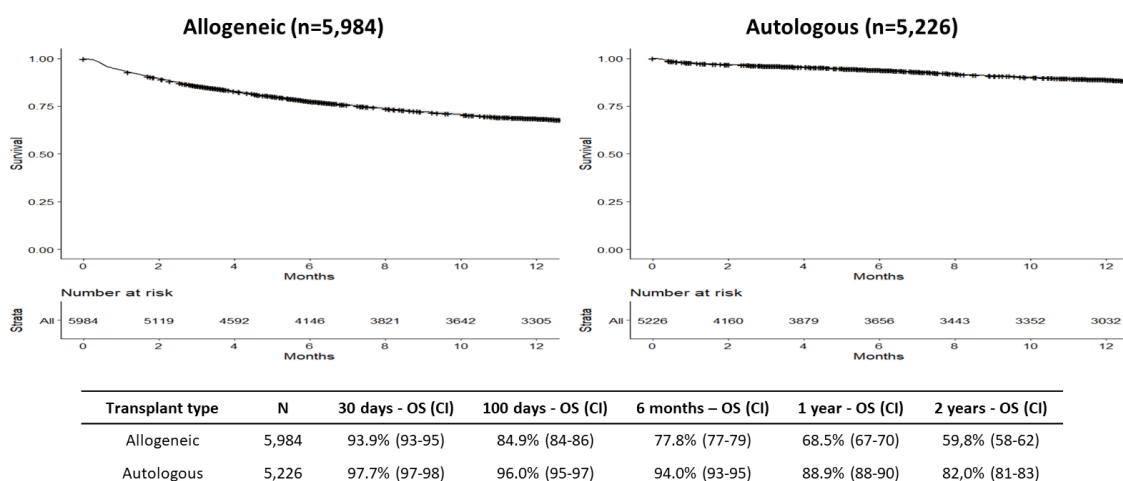


FIGURE 2. Kaplan-Meier curves for overall survival following allogeneic hematopoietic cell transplantation (HCT) in Brazil (2012–2023), stratified by donor type.

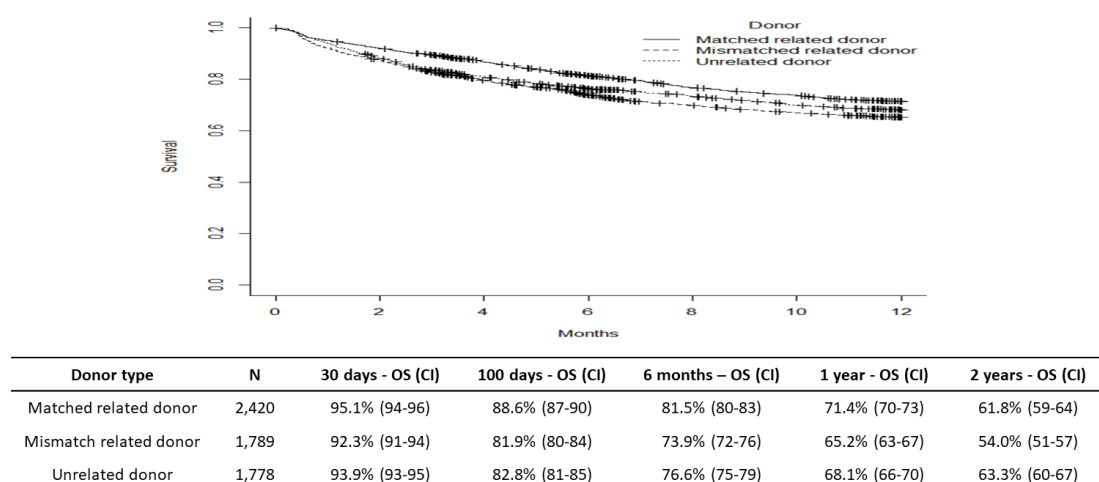
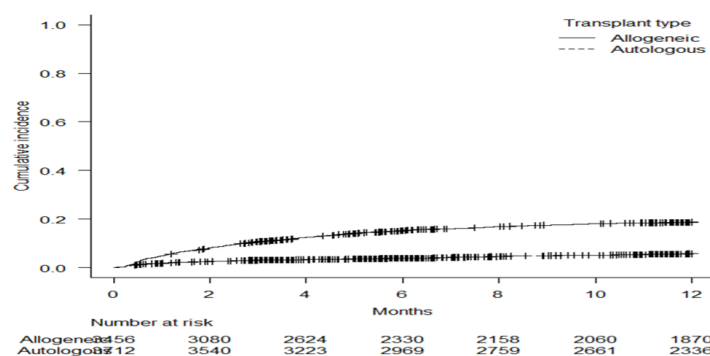
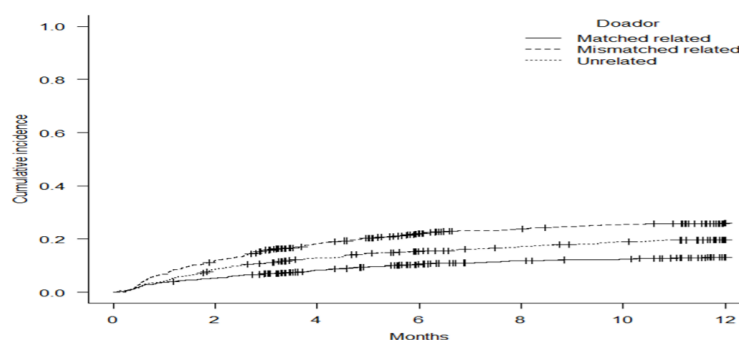


FIGURE 3. Cumulative incidence of non-relapse mortality (NRM) following hematopoietic cell transplantation.



Transplant type	N	30 days – NRM (CI)	100 days – NRM (CI)	6 months – NRM (CI)	1 year – NRM (CI)	2 years – NRM (CI)
Allogeneic	3,456	4.8% (4-6)	11.1% (10-12)	15.1% (14-16)	18.8% (18-20)	21.6% (20-23)
Autologous	3,712	1.8% (1-2)	3.1% (3-4)	3.8% (3-5)	5.7% (5-7)	8.0% (7-9)

FIGURE 4. Cumulative incidence of non-relapse mortality (NRM) after allogeneic hematopoietic cell transplantation by donor type.



Donor type	N	30 days – NRM (CI)	100 days – NRM (CI)	6 months – NRM (CI)	1 year – NRM (CI)	2 years – NRM (CI)
Matched related donor	1,510	3.7% (3-5)	7.2% (6-9)	10.3% (9-12)	13.2% (12-15)	16.3% (14-18)
Mismatch related donor	1,048	6.8% (5-8)	16.3% (14-19)	21.9% (19-25)	26.1% (23-29)	28.1% (25-31)
Unrelated donor	898	4.3% (3-6)	11.6% (10-14)	15.3% (13-18)	19.7% (17-22)	23.0% (20-26)

FIGURE 5. Cumulative incidence of grade II-IV acute graft-versus-host disease (aGVHD) after allogeneic hematopoietic cell transplantation.

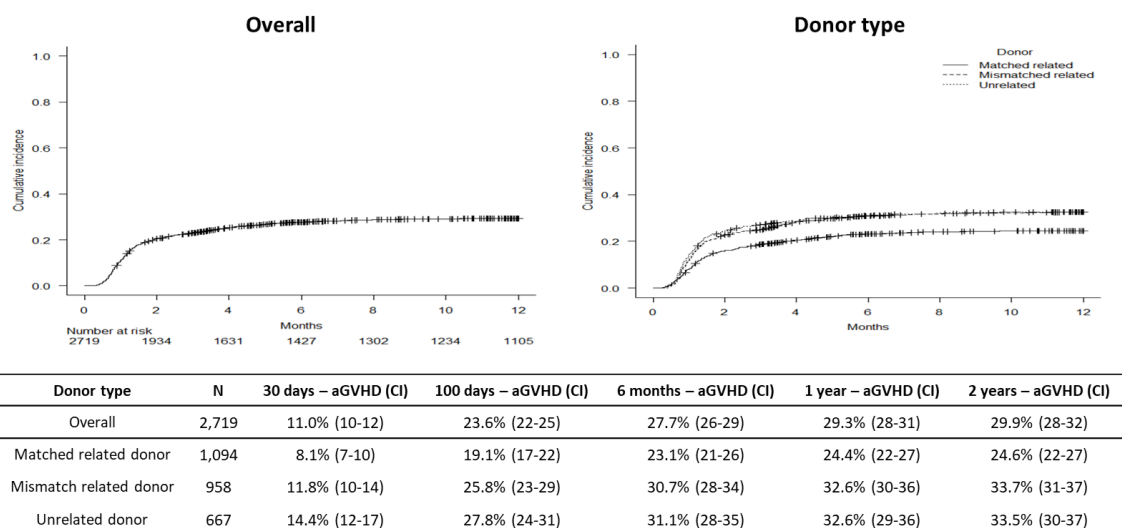


FIGURE 6. Cumulative incidence of grade III-IV acute graft-versus-host disease (aGVHD) after allogeneic hematopoietic cell transplantation.

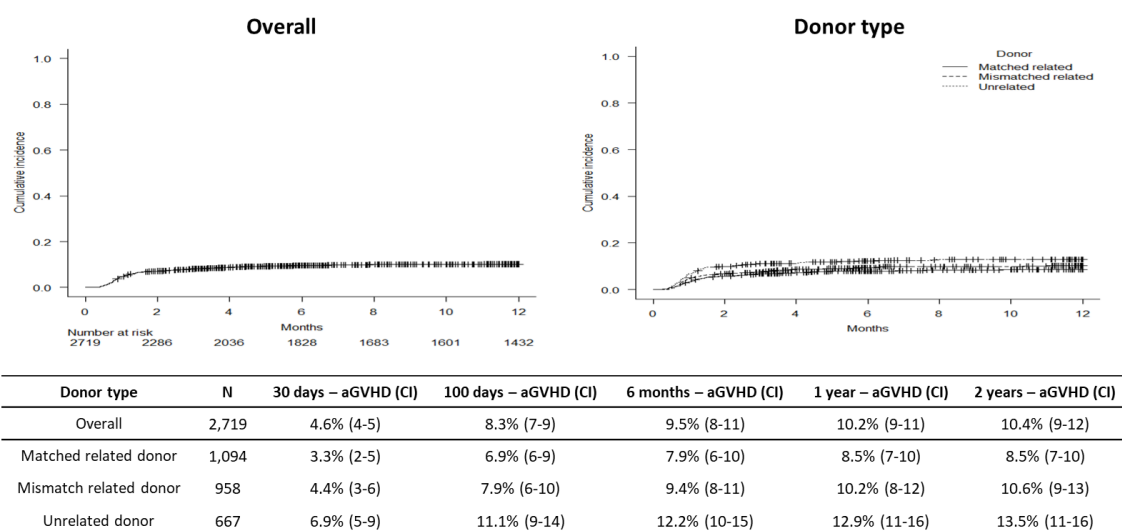


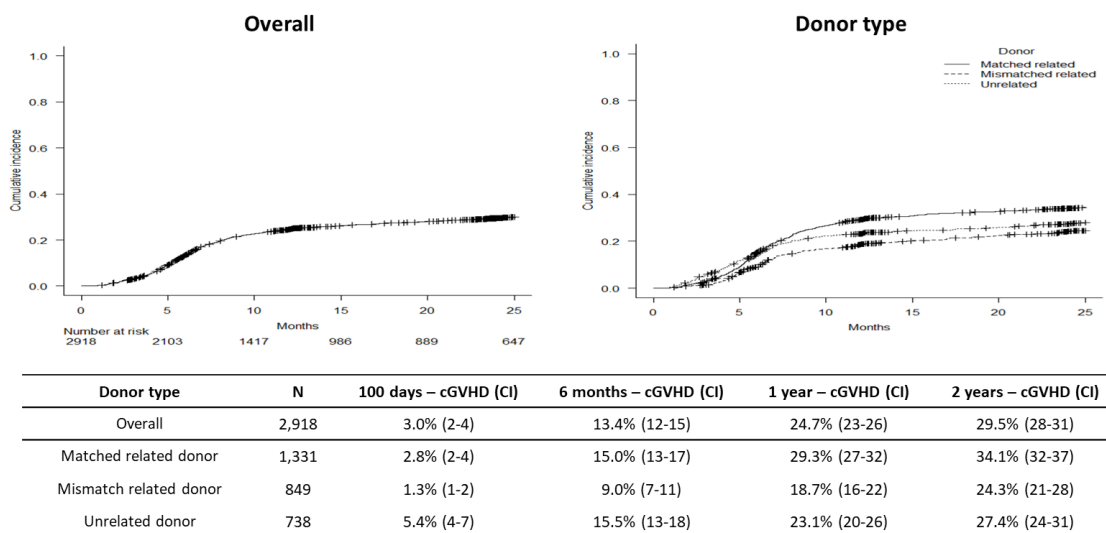
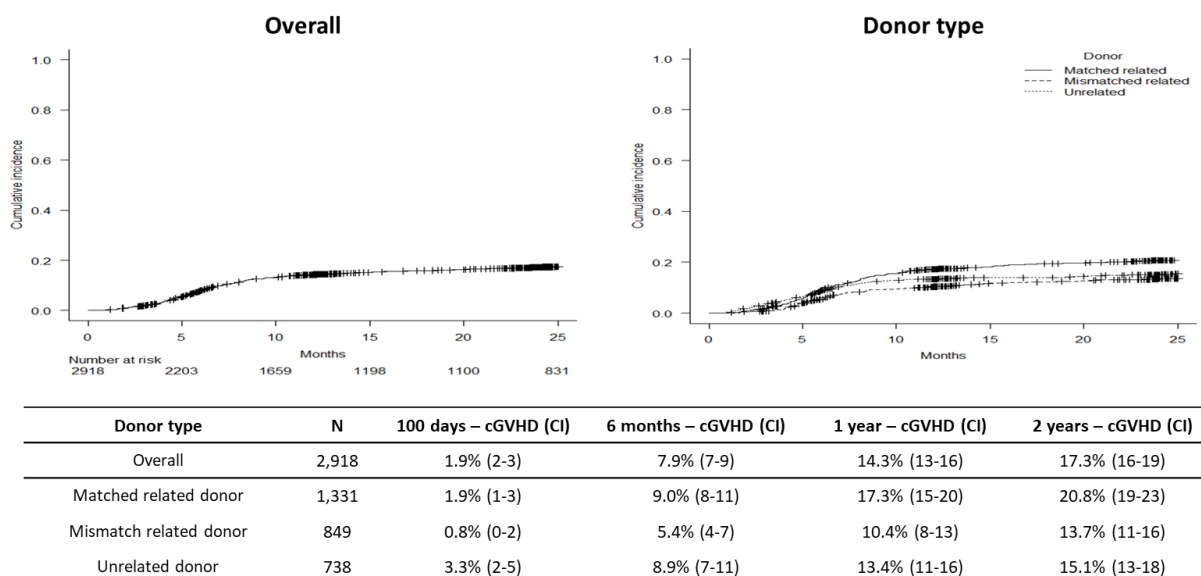
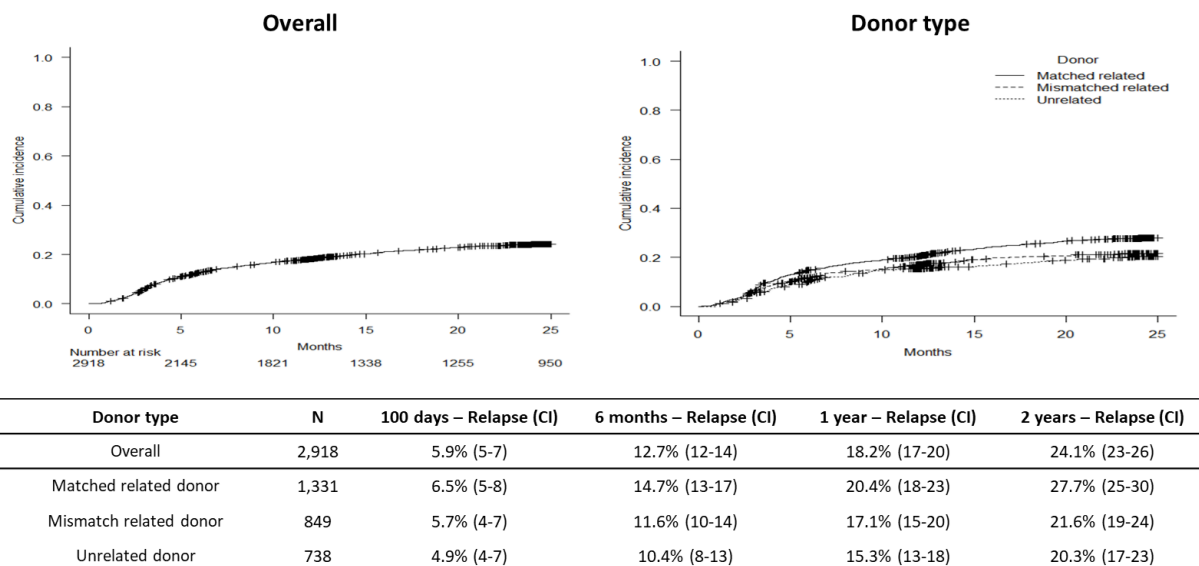
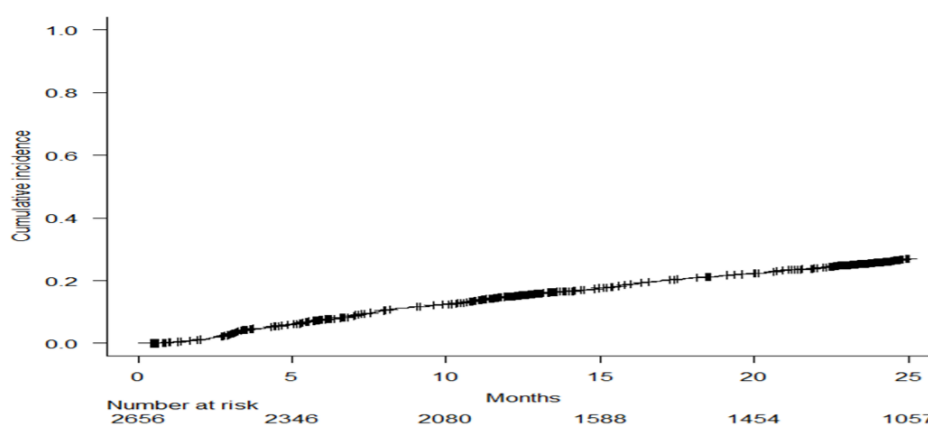
FIGURE 7. Cumulative incidence of any-grade chronic graft-versus-host disease (cGVHD)**FIGURE 8. Cumulative incidence of moderate to severe chronic graft-versus-host disease (cGVHD) in allogeneic transplants.**

FIGURE 9. Cumulative incidence of relapse following allogeneic hematopoietic cell transplantation (HCT).**FIGURE 10.** Cumulative incidence of relapse following autologous hematopoietic cell transplantation (HCT).

Transplant type	N	100 days – Relapse (CI)	6 months – Relapse (CI)	1 year – Relapse (CI)	2 years – Relapse (CI)
Autologous	2,656	3.0% (2-4)	7.6% (7-9)	15.0% (14-16)	25.8% (24-28)

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