



2017 Stem Cell Transplantation Annual Report



Carolinas HealthCare System
Levine Cancer Institute

Overview

At Carolinas HealthCare System's Levine Cancer Institute, we established the Adult Stem Cell Transplant Program in 2012. Our program specializes in matched, related and haploidentical transplants with a comprehensive quality management program, advanced cell processing laboratory and a stem cell collection unit. In March 2014, we performed our first transplant and received accreditation March 2016 from the Foundation for the Accreditation of Cellular Therapy.

With over 20 locations throughout the region, including the site at Carolinas Medical Center in Charlotte, NC, Levine Cancer Institute's success is driven by the impact we have on our community and the patients we serve through innovation and clinical research.

Stem Cell Transplants Performed

More than 20,000 stem cell transplants are performed annually for hematologic malignancies in the United States. Of these transplants, approximately 60 percent are allogeneic and 40 percent are autologous.

At Levine Cancer Institute, autologous and allogeneic transplants have been increasing annually with most allogeneic transplants relying on haploidentical donor sources.

Table 1 Transplants Performed at Levine Cancer Institute 2014-2017

	2014	2015	2016	2017*	Total
Autologous	45	54	71	20	190 (70.11 percent)
MRD	5	10	7	3	25 (9.23 percent)
Haploidentical	10	17	26	3	56 (20.66 percent)
Total	60 (22.14 percent)	81 (29.89 percent)	104 (38.38 percent)	26 (9.59 percent)	271 (100 percent)

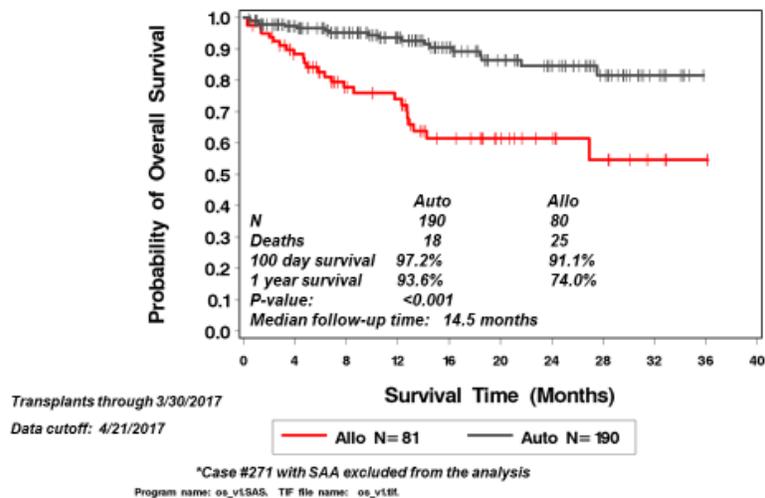
*Transplant statistics through March 30, 2017

Transplantation Survival Outcomes by Type

Autologous transplantation is generally performed for plasma cell disorders, mainly multiple myeloma, and relapsed lymphoma. Autologous transplantation relies upon high-dose chemotherapy and uses the patient's own stem cells to rescue the patient's marrow from this chemotherapy. At the data cutoff of April 21, 2017, 100-day and one-year survival rates in the autologous transplantation population were 97.2 percent and 93.6 percent, respectively.

Allogeneic transplantation is usually performed for acute and chronic leukemias and sometimes for relapsed lymphoma and multiple myeloma. Allogeneic transplantation relies predominantly upon the immune effects of the donor's cells to treat the recipient's cancer. At the data cutoff, 100-day and one-year survival rates in the allogeneic transplantation population were 91.1 percent and 74.0 percent, respectively.

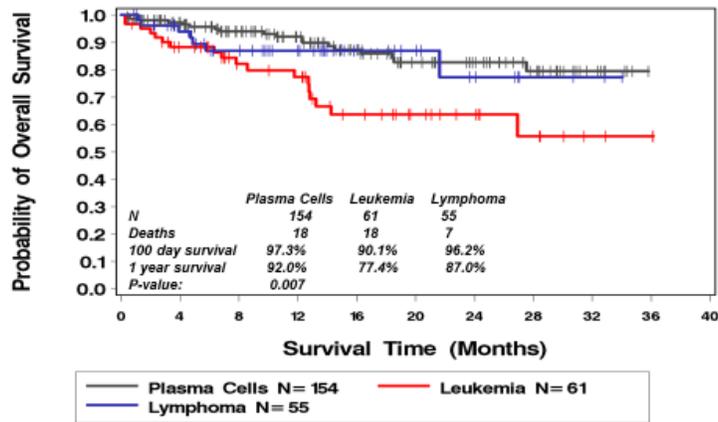
Figure 1 Overall Survival by Transplant Type (N=270*)



Transplantation Survival Outcomes by Disease

As expected, patients with plasma cell disorders and lymphoma, the majority of whom received autologous transplantation, exhibited superior overall survival compared to leukemia patients. One-year survival in the plasma cell group was 92.0 percent compared to 87.0 percent in the lymphoma population and 77.4 percent in the leukemia population.

Figure 2 Overall Survival by Disease (N=270*)



Program name: os_vLSAS. TIF file name: os_dis_vL11f.

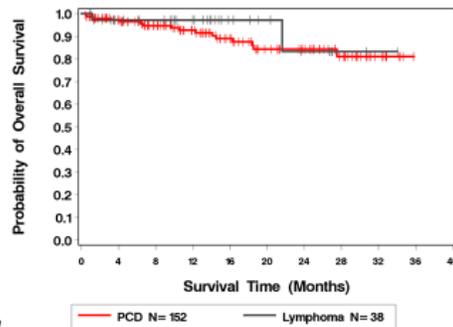
Transplants through 3/30/2017

*Case #271 with SAA excluded from the analysis

Data cutoff: 4/21/2017

Figure 3 displays the overall survival curves for plasma cell disorder and lymphoma patients undergoing autologous transplantation.

Figure 3 Overall Survival by Diseases in Auto Transplant (N=190)



Transplants through 3/30/2017

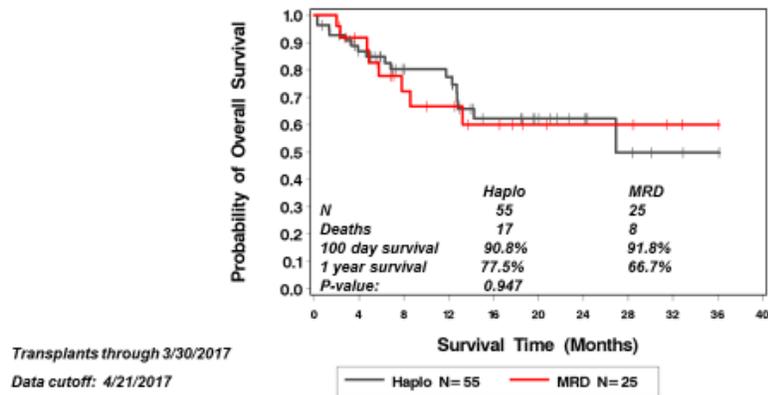
Data cutoff: 4/21/2017

Program name: os_vLSAS. TIF file name: os_pcd_vL11f.

Survival Outcomes by Allogeneic Transplant Type

At the time of data analysis, matched related and haploidentical related donors (but not yet matched unrelated donors) were being used at Levine Cancer Institute with most allogeneic transplants sourced by haploidentical donors. Thus far, survival rates have been similar between the haploidentical and matched related donor groups.

Figure 4 Overall Survival by Allogeneic Type (N=80*)



Program name: os_v15A5. TF file name: os_als_v151.

*Case #271 with SAA excluded from the analysis

Non-Relapse Mortality at Levine Cancer Institute

Non-relapse mortality (NRM) is widely accepted as the most dreaded complication of stem cell transplantation. For autologous transplantation, one-year and overall NRM rates have both been 2.5 percent, whereas for allogeneic transplantation one-year and overall NRM rates have both been 10.7 percent.

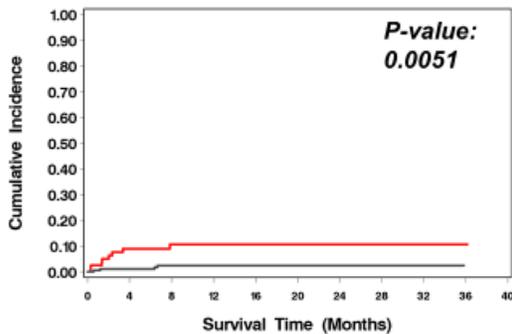
Table 2 Non-relapse Mortality by Transplant (N=270*)

	Auto (N=190)	Allo (N=80)
	Death (%**)	
30 Day Non-relapse Mortality	1 (0.5)	2 (2.5)
100 Day Non-relapse Mortality	2 (1.1)	6 (7.6)
1 Year Non-relapse Mortality	4 (2.5)	8 (10.7)
Overall Non-relapse Mortality	4 (2.5)	8 (10.7)

*Case #271 with SAA excluded from the analysis
 **Rates estimated with cumulative incidence for non-relapse mortality including relapse-related deaths as a competing risk

Transplants through 3/30/2017
 Data cutoff: 4/21/2017

Figure 5 *Cumulative Incidence of Non-relapse Mortality (N=270*)*



Transplants through 3/30/2017
 Data cutoff: 4/21/2017

Program name: NRM_v1.SAS TIF file name: NRM_v2.EE

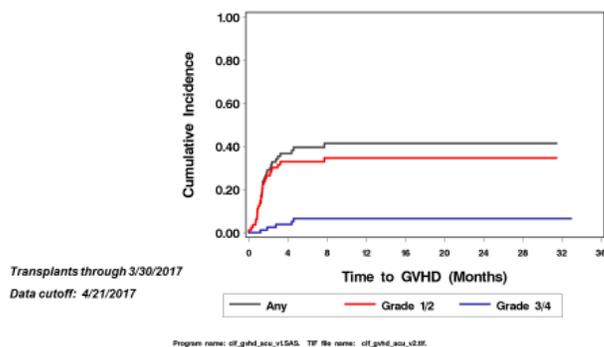
*Case #271 with SAA excluded from the analysis

Figure 5 is a graphical representation of the data in Table 2.

Graft-Versus-Host Disease Complications

With possible rare exceptions, graft-versus-host disease (GVHD) is a complication restricted to allogeneic transplantation. This disease entity occurs when the immune system of the donor attacks the body of the recipient. GVHD comes in two main forms – acute GVHD (aGVHD) and chronic GVHD (cGVHD). Acute GVHD generally occurs within the first 100 days following transplantation, and chronic GVHD usually occurs later. Acute GVHD can be graded on a scale from 1 to 4. There is some evidence that milder aGVHD (grade one or two) correlated with a better “graft versus leukemia” effect, which can help to protect against relapse in patients undergoing allogeneic transplantation. There is also some evidence to suggest that the benefits of aGVHD are outweighed by complications when aGVHD becomes more severe (grade three or four).

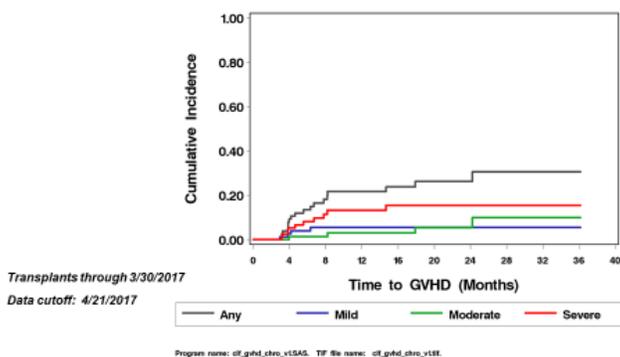
Figure 6 Cumulative Incidence of Acute GVHD by Maximum Severity* (N=81)



Published acute GVHD rates are approximately 39-59%
(Blood. 2012;119(1):296.)

Chronic GVHD can be categorized as mild, moderate or severe and is divided as such in Figure 7.

Figure 7 Cumulative Incidence of Chronic GVHD by Maximum Severity* (N=81)



Published 5-year cumulative chronic GVHD Rate is approximately 45%
Bone Marrow Transplant. 1998;22(8):755.

Summary

Levine Cancer Institute is committed to improving outcomes by providing innovative and supportive care to patients with hematologic malignancies, including those undergoing stem cell transplantation. With multiple ongoing research projects, our team is focused on advancing treatment options and improving care for our transplant patients.



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