Non-Hodgkin's Lymphoma: Five-year Survival in a Historical Cohort of Patients who Underwent Stem Cell Transplantation in Brazil

Linfoma Não-Hodgkin: Sobrevida de Cinco Anos em uma Coorte Histórica de Pacientes Submetidos a Transplante de Células-Tronco no Brasil Linfoma No-Hodgkin: Supervivencia de Cinco Años en una Cohorte Histórica de Pacientes Sometidos a Trasplante de Células Madre en Brasil

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Abstract

Introduction: Several studies have shown the benefits of stem cell transplantation in the treatment of Non-Hodgkin's lymphoma. Objective: To evaluate survival and associated factors in transplanted Non-Hodgkin's lymphoma patients in Brazil. Method: We conducted a retrospective analysis of 100 adult patients with Non-Hodgkin's lymphoma transplanted in a national reference center for hematopoietic stem cell transplantation between 1997 and 2009. Data was obtained from medical charts and included besides socio-demographic and lifestyle variables, others related to diagnosis and transplantation. The five-year survival probability was estimated using the Kaplan-Meier method and differences between curves were tested with the log-rank test, assuming statistical significance level of 5%. Cox regression was performed for multivariate analysis. Results: Median age at diagnosis was 43 years (17-65) and 45 years (18-66) at transplantation. Median time between diagnosis and transplantation was 17 months (4-173). The probability of survival at 5 years was 50.8% with a median survival time of 22.5 months. In multivariate analysis, evidence of disease 12 months after transplant (HR: 4.49; 95% CI 2.15-9.39), chemo-sensitivity to the last regimen before transplant (HR: 2.92; 95% CI 1.35-6.32) and advanced stage at diagnosis (HR: 1.96, 95% CI 1.02-3.80) were prognostic factors for survival. Conclusion: Median age at transplantation in this cohort was similar to that of other studies but median time between diagnosis and transplantation was higher. Although overall survival (5 years) approached that reported in other studies, different treatment protocols and specific characteristics of each population limit comparisons.

Key words: Lynphoma, Non-Hodgkin; Stem Cell Transplantation; Survival Analysis; Survival Rate; Cancer Care Facilities; Brazil

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INTRODUCTION

Half of the patients with Non-Hodgkin's lymphoma (NHL) are cured with first line chemotherapy alone¹. Thus, stem cell transplantation has been regarded as a preferential treatment, especially in patients with sensitive relapse² and this cancer is currently among one of its main indications³.

Several studies have shown the benefits of stem cell transplantation in the treatment of NHL and improved overall survival and disease-free survival was observed even in patients with poor prognosis⁴⁻⁷.

The objective of this study was to evaluate 5-year survival and associated factors in transplanted Non-Hodgkin's lymphoma patients in Brazil.

METHOD

We conducted a retrospective analysis of a cohort of adult patients with NHL who were transplanted between 1997 and 2009 in a national reference centre for oncology and haematopoietic stem cell transplantation in Brazil.

Between April 1997 and April 2009, one hundred adults (18+yr) with NHL underwent transplantation. Data was obtained from medical charts and included socio-demographic and lifestyle information and variables related to the diagnosis and the transplantation.

Overall survival (5 yr) was defined as time (in months) from transplantation until death from any cause and the surviving patients were censored at the last date of follow-up. Patients undergoing a second transplantation within the follow-up period were censored on the date of that procedure.

The probability of survival was estimated using the Kaplan-Meier method and differences between survival curves were checked with the log-rank test, considering statistical significance level of 5%.

Multivariate analysis was performed through Cox regression. Variables showing statistical significance in bivariate analysis ($p \le 0.20$) or considered as having clinical significance were tested in the models. Variables were excluded from the model if $p \le 0.05$.

Statistical analysis was performed on the Statistical Package for Social Sciences version 17.0 (SPSS Chicago, IL, USA).

The Ethics Comities of Brazilian National Cancer Institute (n°114/09 in 10/22/2009) and National School of Public Health (n°33/10 in 04/16/2010) approved this study.

RESULTS

The majority of the study population were male (61.0%) and had 30-49 years of age (47.5%). Median age at diagnosis was 43 years [17-65] and at transplantation was 45 years [18-66]. Most patients were non-smokers

(61.7%) and non-alcohol drinkers (62.7%). Most had advanced stages of disease (III and IV).

At transplantation the predominant subtype was Diffuse Large B-Cell Lymphoma (DLBCL) and most individuals showed chemosensitivity to the pre-transplant chemotherapy regimen. Patient characteristics at diagnosis and transplantation are shown in Tables 1 and 2.

Table 1. Characteristics of patients at diagnosis of NHL (N=100)

able 1. Characteristics of patients at diagnos	is of NHL (ſ	4=100)			
Variables	N	%			
Gender					
Male	61	61.0			
Female	39	39.0			
Age (years)					
< 30	24	24.2			
30 – 49	47	47.5			
≥ 50	28	28.3			
Tobacco use		_			
Yes	7	8.6			
No	50	61.7			
Ex-user	24	29.6			
Alcohol use					
Yes	22	32.8			
No	42	62.7			
Ex-user	3	4.5			
NHL subtype					
Diffuse large cell	72	72.0			
Follicular	16	16.0			
Lymphoblastic	2	2.0			
Lymphocytic	1	1.0			
Burkitt	2	2.0			
Mantle cell	3	3.0			
MALT	2	2.0			
T cell	1	1.0			
Not classified	1	1.0			
Stage					
1	8	9.5			
II	20	23.8			
III	20	23.8			
IV	36	42.9			
Mediastinal mass		_			
Yes	22	23.9			
No	70	76.1			
Bone marrow involvement	_	_			
Yes	16	18.8			
No	69	81.2			
Bulky Disease					
Yes	34	43.6			
No	44	56.4			
B symptoms					
Yes	42	49.4			
No	43	50.6			
Serum lactatate dehydrogenase concentration					
≤460	23	39.7			
>460	35	60.3			

Table 2. Characteristics of patients at transplantation (N=100)

Table 2. Characteristics of patients at transpla	·				
Variables	N	%			
Age (years)					
< 30	16	16.0			
30-49	49	49.0			
≥ 50	35	35.0			
NHL subtype					
Diffuse large cell	82	82.0			
Follicular	7	7.0			
Lymphoblastic	2	2.0			
Lymphocytic	2	2.0			
Burkitt	2	2.0			
Mantle cell	3	3.0			
T cell	1	1.0			
Not classified	1	1.0			
Conditioning regimen					
CBV*	76	79.2			
fludarabine + cyclophosphamide	13	13.5			
TBI** + cyclophosphamide	3	3.1			
Other	4	4.2			
Disease status					
1 st complete response	6	6.1			
2 nd or more complete responses	19	19.2			
1 st relapse	39	39.4			
2 nd or more relapses	14	14.1			
Primary induction fail	17	17.2			
Other	4	4.0			
Chemosensitivity to last pre-transplant regimen					
Sensitive	83	83.0			
Resistant	10	10.0			

^{*}CBV - cyclophosphamide, bis-chloroethylnitrosourea, and etoposide

**TBI - Total body irradiation

Median time between diagnosis and transplantation was 17 months [4-173]. Autologous stem cell transplantation was performed in 84 patients and allogeneic transplantation in 16 patients. The most frequent side effect was mucositis [n = 63].

Twenty-nine patients died during the first twelve months after transplantation and 44 thereafter. The probability of survival at 5 years was 50.8% with a median survival time of 22.5 months. In the first year of follow-up 28 patients presented evidence of disease and at 5 years, 36. Survival free of evidence of disease at 5 years was 54.2% with a median time of 16 months.

Individuals with bulky disease had shorter survival than those without it (36.7% vs. 60.6%, p=0.045). In the first 12 months after transplantation survival was lower in patients showing evidence of disease (5.7% vs. 67.5%, p<0.001). The same happened in the five-year follow-up (8.0% vs. 72.2%, p<0.001) (Table 3).

Patients with advanced stage disease at diagnosis had a higher probability of survival than those at the initial stages (61.9% vs. 31.8%, p = 0.016) (Table 3). However, when analyzing survival according to strata of chemosensitivity at transplantation it was observed that among patients sensitive to last pre-transplant regimen, survival was better than among those at advanced stages (p=0.016).

Meanwhile, in the strata of patients resistant to last pre-transplant regimen there was no difference in survival by stage (Figure 1). Concerning disease status at transplantation, it was observed that among those patients showing a complete response, those at advanced stages showed better survival (p=0,018) (Figure 2).

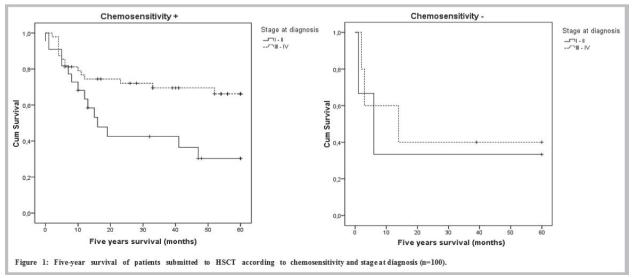


Figure 1. Five-year survival of patients submitted to HSCT according to chemosensitivity and stage at diagnosis (n=100)

Table 3. Overall survival (OS) and disease-free survival (DFS) (5 years) for patients submitted to HSCT according to socio-demographic and clinical characteristics (N=100)

Variables	os	*p-value	DFS	*p-value
Gender				
Male	50.3	0.648	59.0	0.480
Female	5.0		48.0	
Age at diagnosis (years)				•
< 50	53.3	0.694	56.0	0.313
≥ 50	43.0		48.8	
Mediastinal mass	'			
Yes	35.7	0.356	38.9	0.674
No	51.9		55.1	
Bone marrow involvement	'			
Yes	75.0	0.062	68.4	0.071
No	42.4		50.6	
Serum lactate dehydrogenase concentration		' '		'
≤460	62.3	0.155	53.6	0.631
>460	47.7		53.7	
NHL subtype at HSCT	1	' '		1
Diffuse large cell	50.1	0.546	51.5	0.238
Follicular	64.3		53.6	5.255
Other	34.3		88.9	
Stage	01.0	1 1	33.7	ı
l e II	31.8	0.016	45.2	0.127
III e IV	61.9	0.010	61.4	0.127
Bulky Disease	01.7	1 1	01.4	ı
Yes	36.7	0.045	42.1	0.037
No	60.6	0.043	60.5	0.007
B symptoms	00.0	1 1	00.5	ı
Yes	43.8	0.191	52.7	0.434
No	56.5	0.171	54.5	0.454
Age at HSCT (years)	30.3	1 1	34.3	ı
< 50	51.7	0.981	53.2	0.760
≥ 50	49.3	0.701	55.2 55.4	0.700
Disease status at HSCT	47.3	1 1	33.4	I
Complete response	62.8	0.420	67.5	0.324
•	46.2	0.420	48.8	0.324
Relapse Primary induction fail	55.8		46.6 66.6	
•	55.6	1 1	00.0	I
Chemosensitivity to last regimen Sensitive	52.0	0.005	50.0	0.500
	53.8	0.095	52.8	0.590
Resistant	40.0	1 1	70.0	I
Type of HSCT		1 07/5	0.4.4	1 0000
Alogenic	61.9	0.765	84.4	0.080
Autologous	49.0	1 1	49.6	I
Evidence of disease post-HSCT (1year)	l	0.555		1
Yes	5.7	0.000	-	
No	67.5		-	I
Evidence of disease post-HSCT (5 years)	1	1 1		
Yes	8.0	0.000	-	
No	72.2	1	-	

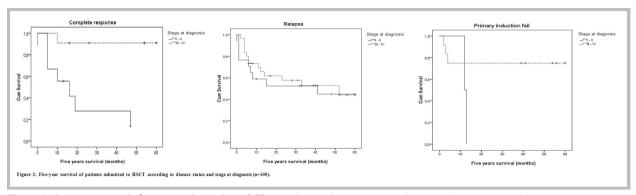


Figure 2. Five-year survival of patients submitted to HSCT according to disease status and stage at diagnosis (n=100)

In multivariate analysis, the variables that remained in the model for 5-year survival were: evidence of disease 12 months after transplant (HR: 4.49, 95% CI 2.15-9.39), chemosensitivity to the last regimen before transplant (HR: 2.92; 95% CI 1.35-6.32) and advanced stage at diagnosis (HR: 1.96, 95% CI 1.02-3.80).

A separate analysis was performed in the subgroup of 75 patients with diagnosis of DLBCL that underwent autologous transplantation. The observed results were similar to those for the entire population, except for multivariate analysis in which only the variable "evidence of disease 12 months after transplant" remained in the model.

DISCUSSION

We conducted a retrospective analysis of a cohort of all patients (100) that underwent this procedure at the referral center during the study period.

The median age at diagnosis was lower than that observed in a study with data from Central and South America (59 years)⁸. However this study population was differentiated as it included only transplanted patients. Similarly to other studies, we found a majority of men among the patients^{9,10}.

The role of alcohol intake in the risk of NHL is still largely unclear^{11,12}. However, a recent meta-analysis found an association between alcohol drinking and NHL¹². In relation to tobacco, some studies found evidence of an association with NHL^{13,14}. However, our data is only descriptive and does not allow this kind of analysis.

The median age at transplantation in this cohort was similar to that observed in other studies^{15,16}. However, the upper age limit for transplantation in our study suggests that this procedure has been performed particularly in younger subjects, unlike what is seen in other countries^{7,15}.

The median time between diagnosis and transplantation in our cohort was higher than that found in other studies^{4,17,18,19}. This may be indicating that the decision to include this procedure in the treatment of NHL was a more recent option in our midst.

Some characteristics of our cohort, such as the high frequency of the DLBCL subtype^{5,19,20,21}, advanced stage (III-IV)^{1,2,22,23} and presence of bulky disease¹ and B symptoms^{1,4} were similar to those observed in other studies. When compared to the only other study conducted in Brazil²⁴, the median age at transplantation and the prevalence of subtype DLBCL were similar.

Mucositis was the most common side effect of treatment in our cohort. This complication has been reported in other studies of patients undergoing haematopoietic stem cell transplantation^{2, 6,15}.

Although the overall survival (5 years) in our cohort approached that of other studies^{5,7,16,24}, the different treatment protocols, as well as the specific characteristics of each study population, limit this comparison.

In the survival analysis performed with the Kaplan-Meier method, statistically significant differences in survival curves were observed for presence of bulky disease, evidence of disease 12 months after transplantation and advanced stage. The presence of bulky disease resulted in lower overall survival (5 yr). This finding was also observed in another study conducted in Italy with 134 patients⁴. Similarly, the evidence of disease 12 months after transplantation resulted in poor survival. In the first two years after transplantation relapse or progression of the disease was the most common treatment failure in other study¹⁹.

Advanced disease stage resulted in improved survival, but that could be a chance finding due to the size of the studied population. When evaluating survival in the strata of chemosensitivity (sensitive and resistant) this condition was more relevant to survival than disease stage. The observation of better survival in patients with advanced disease at diagnosis could be related to the fact that these patients presented a better response to chemotherapy. Disease status at transplantation (complete response and relapse) was also more relevant to survival than the disease stage.

Evidence of the disease in the first 12 months post transplant and chemosensitivity to the last regimen before transplant were prognostic factors associated with poor survival (5 yr) in multivariate analysis. Evidence of the disease in the post-transplant stages^{18,21} and chemosensitivity^{3,4,6,25} were also prognostic factors for overall survival in other studies. Advanced disease stage was also significantly associated with poorer survival in our study, but the lower limit of the confidence interval was very close to the unity.

The small number of individuals comprising the study population made it difficult to observe statistically significant associations in the analysis. However, all the NHL patients of the referral center who were transplanted during the 12-year study period were included in the analysis.

The heterogeneity observed in our cohort limits the interpretation of the results and may indicate changes in treatment protocols during the study period, a fact that was also observed in the literature.

On the other hand, this is one of the few Brazilian studies that analyzed survival and its associated factors in patients with NHL who underwent transplantation. Therefore, its findings could contribute to the understanding of important prognostic factors that may, in part, be reflecting unique aspects of the treatment of lymphoma Non-Hodgkin in our country.

CONCLUSION

Median age at transplantation in this cohort was similar to that of other studies but median time between diagnosis and transplantation was higher. Although overall survival (5 years) approached that related in other studies, different treatment protocols and specific characteristics of each population limit comparisons.

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CONTRIBUTIONS

Laércio Lima Luz and Inês Echenique Mattos contributed to: study concepts, study design, data acquisition, quality control of data and algorithms, data analysis and interpretation, statistical analysis, manuscript preparation, manuscript editing and manuscript review.

Alexandre Mello de Azevedo contributed to: data acquisition, quality control of data and algorithms and data analysis and interpretation.

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Resumo

Introdução: Diversos estudos mostram os benefícios do transplante de células-tronco no tratamento do linfoma não-Hodgkin. Objetivo: Avaliar a sobrevida e fatores associados em pacientes com linfoma não-Hodgkin transplantados no Brasil. Método: Realizou-se a análise retrospectiva de 100 pacientes adultos com linfoma não-Hodgkin transplantados em centro de referência nacional entre 1997 e 2009. Os dados obtidos dos prontuários médicos incluíam variáveis sociodemográficas e de estilo de vida relacionadas ao diagnóstico e transplante. Estimou-se a probabilidade de sobrevida de cinco anos pelo método de Kaplan-Meier e testaram-se as diferenças entre as curvas com o teste do log-rank, assumindo nível de significância de 5%. A regressão de Cox foi utilizada na análise multivariada. Resultados: A idade mediana ao diagnóstico foi 43 anos (17-65) e 45 anos (18-66) ao transplante. O tempo mediano entre diagnóstico e transplante foi 17 meses (4-173). A probabilidade de sobrevida (5 anos) foi 50,8% e o tempo mediano de sobrevida de 22,5 meses. Na análise multivariada, evidência de doença 12 meses após o transplante (HR:4,49; IC 95% 2,15-9,39), quimiossensibilidade ao último regime antes do transplante (HR: 2,92; IC 95% 1,35-6,32) e estágio avançado ao diagnóstico (HR: 1,96; IC 95% 1,02-3,80) foram fatores prognósticos. Conclusão: A mediana de idade ao transplante nesta coorte foi similar à de outros estudos, mas o tempo mediano entre o diagnóstico e o transplante foi mais alto. A sobrevida global se aproximou da de outros estudos, mas diferenças nos protocolos de tratamento e características especificas de cada população limitam a comparação.

Palavras-chave: Linfoma não Hodgkin; Transplante de Células-Tronco; Analise de Sobrevida; Taxa de Sobrevida; Instituto de Câncer; Brasil

Resumen

Introducción: Diversos estudios demuestran los beneficios del trasplante de células madre en el tratamiento del linfoma no-Hodgkin. **Objetivo:** Evaluar la supervivencia y los factores asociados en pacientes con linfoma no-Hodgkin trasplantados en Brasil. **Método:** Se realizó el análisis retrospectivo en 100 pacientes adultos con linfoma no-Hodgkin, trasplantados en un centro de referencia nacional entre 1997 y 2009. Los datos obtenidos de registros médicos incluían variables socio-demográficas y de estilo de vida vinculadas al diagnóstico y al trasplante. Se estimó la probabilidad de supervivencia de 5 años por el método de Kaplan-Meier y las diferencias entre las curvas fueron probadas con el test de log-rank, asumiendo nivel de significación del 5%. Regresión de Cox se utilizó para el análisis multivariado. **Resultados:** El promedio de edad del diagnóstico fue de 43 años (17-65) y de 45 años (18-66) al trasplante. El promedio de tiempo entre diagnóstico y trasplante fue de 17 meses (4-173). La probabilidad de supervivencia fue del 50,8% y la supervivencia promedio de 22,5 meses. En el análisis multivariado, evidencia de enfermedad 12 meses después del trasplante (HR: 4,49, IC 95% 2,15-9,39), quimio-sensibilidad al último régimen antes del trasplante (HR: 2,92, IC 95% 1,35 a 6,32) y estado avanzado al diagnóstico (HR: 1,96, IC 95% 1,02-3,80) fueron factores pronosticados. **Conclusión:** El promedio de edad al trasplante fue similar al de otros estudios, pero el promedio de tiempo entre diagnóstico y trasplante fue mayor. La supervivencia global se acercó a los otros estudios, pero diferencias en los protocolos de tratamiento y características específicas de cada población limitan las comparaciones.

Palabras clave: Linfoma no Hodgkin; Transplante de Células Madre; Analísis de Supervivencia; Tasa de Supervivencia; Instituciones Oncológicas; Brasil