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Allogeneic – Adult

Deauville Scores 4 or 5 Assessed by Fluorine-18 Fluorodeoxyglucose Positron Emission Tomography/Computed Tomography Early Post-Allotransplant Is Highly Predictive of Relapse in Lymphoma Patients

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A B S T R A C T

The impact of early fluorine-18 fluorodeoxyglucose positron emission tomography/computed tomography (FDG PET-CT) status on survival after allogeneic transplantation for lymphoma is poorly reported. This retrospective study included all adult Hodgkin lymphoma (HL) or non-Hodgkin lymphoma(NHL) patients (>18 years old) who benefited from FDG PET-CT before (within 1 month) and/or early (+3 months and within +6 to 9 months) after allogeneic stem cell transplantation in our institution between 2005 and 2015 and who were still without documented progression or relapse at the time of the FDG PET-CT. All FDG PET-CT were reviewed by a nuclear medicine expert in hematology and restaged according to the Deauville scale. FDG-PET CT was considered positive when the uptake was higher than liver background (Deauville score ≥ 4). The primary objective was to study the impact of pre- and post-transplant FDG PET-CT on lymphoma-free survival (LFS) and overall survival (OS). Inclusion criteria were fulfilled for 103 patients (69 men; median age, 51.6 years old; range, 22 to 67). Diagnoses were high-grade NHL (n = 47), low-grade NHL (n = 6), T cell lymphoma (n = 34), and HL (n = 16). More than half of the patients were in complete remission at the time of transplant (n = 56). A reduced-intensity conditioning regimen was applied in most cases (n = 90). With a median follow-up of 49.5 months (range, 6 to 140.5) for alive patients, median 3-year OS and LFS were, respectively, 81% (range, 71% to 87%) and 65% (range, 54% to 74%) for the entire cohort. In multivariate analysis, positive FDG PET-CT at 3 months was the strongest independent factor significantly associated with poorer LFS (hazard ratio, 9.22; 95% confidence interval, 1.88 to 645.2; $P = .006$). FDG PET-CT positivity at 3 months appears to be highly predictive of LFS in patients after allogeneic transplantation and may help to guide strategies to prevent relapse. These results need to be validated prospectively.

INTRODUCTION

The use of allogeneic stem cell transplantation (Allo-SCT) for non-Hodgkin lymphoma (NHL) or Hodgkin lymphoma (HL) is increasing as reported recently by the European Society for Blood and Marrow Transplantation [1]. This represents, respectively, 8% and 2% of all Allo-SCTs currently performed in Europe. Allo-SCT is most often the only potentially curative treatment for selected patients with relapsed and refractory lymphoma, especially when relapse occurs after autologous SCT [2,3].

Because relapse still occurs after Allo-SCT for lymphoma, strategies to predict and avoid disease recurrence to improve survivals are urgently needed. Fluorine-18 fluorodeoxyglucose positron emission tomography/computed tomography (FDG PET-CT) has become an established tool for disease staging and response assessment in HL and NHL [4]. For lymphoma patients having received autologous SCT, it has been shown that both pre- and post-transplant FDG PET-CT status are constantly and strongly associated with outcomes [5–12]. The impact of FDG PET-CT before and after Allo-SCT remains more controversial.

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Before Allo-SCT, conflicting results have been published, some of them reporting no influence of PET positivity on survival [13–18], whereas others indicated that the PET status impacted success [12,19]. After Allo-SCT, Ulaner et al. [20] reported that lymphoma-free survival (LFS) was significantly decreased in patients presenting with post-transplant FDG-avid lesions. However, FDG PET-CT was performed at a median of 6 months post-transplant in these series, a period of time often inappropriate to consider prophylactic or preemptive therapy because most relapses have already occurred at that time [21,22]. Because of limited available data regarding this topic, a retrospective analysis was conducted on a large cohort of lymphoma patients to study the influence on survival of FDG PET-CT positivity, early after Allo-SCT, using the Deauville 5-point scale (Deauville score [DS]) as indicated by Lugano's recommendations in lymphoma [23].

METHODS

Study Design

This retrospective study included all adult lymphoma patients (>18 years old) who benefited from FDG PET-CT before (within 1 month) and/or early (+3 months and within +6 to 9 months) after Allo-SCT in our institution between 2005 and 2015 and who were still without documented progression or relapse at the time of the FDG PET-CT. All histologic types of NHL were allowed as well as HL. The primary objective was to study the impact on LFS and overall survival (OS) of pretransplant (within 1 month) and early post-transplant (+3 months and within +6 to 9 months) FDG PET-CT. This study was approved by the ethics review board of Nantes University Hospital. All patients provided informed consent to collect their personal data.

Status at transplant (ie, complete remission, partial response, or active disease) was determined according to the International Working Group Criteria standard criteria before Allo-SCT [24,25]. Active disease was defined as stable disease (<50% reduction in the disease burden), progression (increase of >25% of the disease burden), or refractory disease. Information about CTs, lymph node biopsy examination, and donor lymphocyte infusions after transplant was collected whenever available.

FDG-PET Imaging

Patients were required to fast at least 4 hours before ^{18}F-FDG injection, and blood glucose was controlled before FDG injection. The acquisition of images was performed on a Discovery LS PET/CT (General Electrics Medical Systems) 60 to 80 minutes after intravenous injection of 5 to 7 MBq (135 to 189μCi)/kg of ^{18}F-FDG or on a Biograph mCT (Siemens) 60 to 80 minutes after intravenous injection of 3 MBq (81 μCi)/kg of ^{18}F-FDG. All FDG-PET images were retrospectively reviewed by a nuclear medicine expert experienced in hematology (C.B.M.). FDG-PET positivity was defined as an FDG-uptake greater than liver background, which corresponds to DS ≥ 4 [23].

Statistical Analysis

The clinical outcomes studied were OS, LFS, relapse incidence, and nonrelapse mortality. OS was defined as the time from day 0 of Allo-SCT to death or last follow-up for survivors. LFS was defined as the time from day 0 of Allo-SCT to the date of death or last follow-up without evidence of relapse or disease progression. Relapse or disease progression (relapse incidence) was defined according to the International Working Group standard criteria after transplant [24,25]. Nonrelapse mortality was defined as death from any cause without previous relapse or progression. Probabilities of OS and LFS were calculated using the log-rank test and Kaplan-Meier graphic representation. Cumulative incidence functions [26] were used to estimate relapse incidence and nonrelapse mortality in a competing risk setting. Survival probabilities are presented as percentages and 95% confidence intervals (95% CIs).

Univariate analyses were performed using the log rank test for OS and LFS and the Gray test for cumulative incidence functions. Characteristics considered for univariate analysis were age (< or ≥60 years), gender (male versus female), previous lines of treatment (≤2 versus >2), conditioning regimen (myeloablative versus reduced-intensity conditioning), type of lymphoma (high-grade-NHL versus T lymphoma versus HL), disease status at transplant (complete remission versus partial response), type of donor (sibling versus matched unrelated donor versus alternative donor), DS for FDG PET-CT (≥4 versus <4) before transplant, at 3 months post-transplant, and within 6 to 9 months post-transplant. Multivariate analyses were performed using the Cox proportional hazard model. Factors with $P < .50$ by univariate analysis were included in the multivariate analysis.

All tests were 2-sided, and $P < .05$ was considered as indicating a statistically significant association. Analyses were performed using the R statistical software version 3.2.3 (available online at http://www.R-project.org).

RESULTS

Patient Characteristics

Between April 2005 and December 2015, 103 patients fulfilled the inclusion criteria. There were 69 men (66%), and the median age of the cohort was 51.6 years old (range, 22 to 67). Diagnoses were diffuse large B cell lymphoma (n = 19), diffuse large B cell lymphoma transformation of low-grade lymphoma (n = 15), mantle cell lymphoma (n = 11), Burkitt lymphoma (n = 1), and gray zone lymphoma (n = 1). These patients (n = 47) were considered as having high-grade NHL. The other diagnoses were low-grade NHL (n = 6), T cell NHL (n = 34; peripheral T cell lymphoma not otherwise specified, n = 19; angioimmunoblastic, n = 9; anaplastic large cell, n = 5; natural killer, n = 1)) and HL (n = 16). Sixty-three patients had already received an autologous SCT. Fifty-six patients were considered in complete remission at the time of transplant. Ninety patients received a reduced-intensity conditioning regimen. Patient characteristics are given in Table 1.

Outcomes

With a median follow-up of 49.5 months (range, 6 to 140.5) for alive patients, 3-year OS and LFS were 81% (95% CI, 71 to 87) (Figure 1A) and 65% (95% CI, 54 to 74) (Figure 1B), respectively, for the entire cohort. Twenty-six patients (25.2%) relapsed at a median time of 4.5 months (95% CI, 3 to 15.9) after Allo-SCT.

Table 1
Patient Characteristics (N = 103)

Characteristic	Values
Median follow-up, mo (range)	49.5 (6-140.5)
Median age at transplant, yr (range)	51.6 (22-67)
Age ≥ 60 yr	35 (34)
Gender, male	69 (67.0)
Type of lymphoma	
High-grade B cell NHL*	47 (45.5)
Low-grade B cell NHL†	6 (6)
T-NHL	34 (33)
HL	16 (15.5)
Number of previous treatments	
1	32 (31.2)
2	36 (35.3)
3	25 (24.4)
≥4	9 (8.8)
Previous autologous SCT	63 (61)
Disease status at transplant	
Complete remission	56 (54.4)
Partial remission	40 (38.8)
Active	7 (6.8)
Conditioning regimens	
Reduced intensity	90 (87)
Myeloablative	13 (13)
Source of graft	
Peripheral blood stem cells	88
Bone marrow	6
Cord blood	9
Donor type	
Sibling	43 (42)
Matched unrelated	41 (40)
9/10 mismatched unrelated	5 (5)
Haploidentical	5 (5)
Cord blood	9 (8)
Number of PET CT reexamined	
Pretransplant	81 (78.6)
At +3 mo	93 (90.3)
Within +6 and +9 mo	61 (59.2)

Values are n (%) unless otherwsie defined.

* Including 19 diffuse large B cell lymphoma, 15 diffuse large B cell lymphoma transformed from low-grade lymphoma, 11 mantle cell lymphoma, 1 Burkitt lymphoma, and 1 gray zone lymphoma.

† Including 5 follicular lymphoma and 1 marginal zone lymphoma.

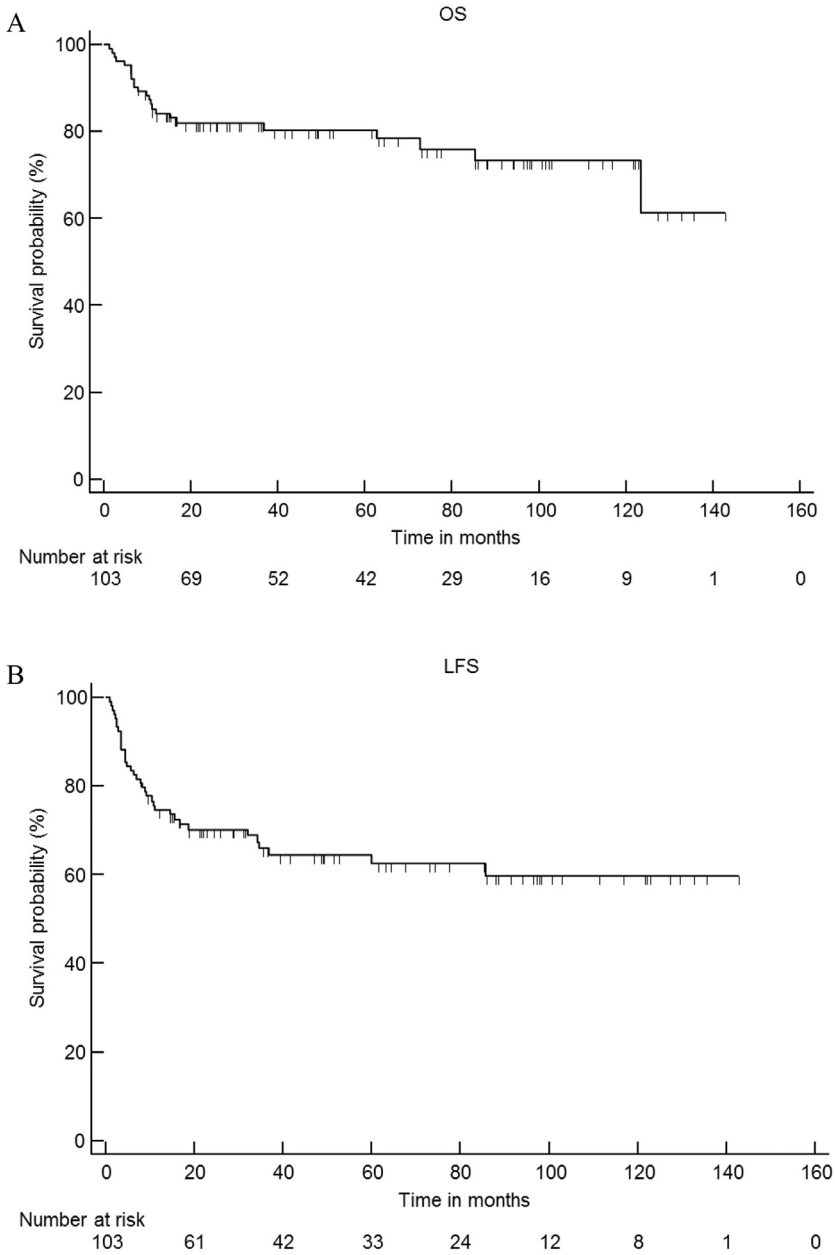

Figure 1. OS (A) and LFS (B) for the entire cohort.

Three-year cumulative incidence of relapse was 25% (95% CI, 8 to 35) and 3-year cumulative incidence of nonrelapse mortality was 13.6% (95% CI, 9.6 to 16.5).

FDG PET-CT Results

FDG PET-CT was positive before transplant for 20 of 81 patients tested (24.6%), at 3 months for 20 of 93 (21.5%), and within 6 to 9 months post-transplant for 18 of 61 (29.5%). Interestingly, none of the low-grade NHL patients ever had a positive FDG PET-CT at any time.

Pretransplant positive FDG PET-CT was not associated with relapse/progression (3-year incidence, 20% versus 26%; P = .79). Conversely, there was a statistically significant association between relapse/progression and positive FDG PET-CT at 3 months (3-year incidence, 50% versus 17.8%; P = .007) and within 6 to 9 months post-transplant (3-year incidence, 44.4% versus 14%; P = .02).

Univariate and Multivariate Analyses

In a univariate analysis (Table 2) positive FDG PET-CT at 3 months was associated with lower OS and LFS (64% [95% CI, 45 to 89] versus 88.6% (95% CI, 81 to 96; P = .02] and 33.3% [95% CI, 17 to 63] versus 77.7% (95% CI, 68 to 88; $P < .0001$], respectively) (Figure 2A,B). The same was noted for FDG PET-CT positivity at 6 to 9 months for LFS (50% [95% CI, 31 to 79] versus 81.8% [95% CI, 69 to 96], P = .002) but not OS. Excluding patients with low-grade NHL did not change these results. Age, type of lymphoma, previous number of lines of treatment, status at transplant, conditioning regimen, and type of donor had no impact on LFS and OS.

In a multivariate analysis (Table 3) FDG PET-CT positivity at 3 months and 6 to 9 months was the only independent factor associated with lower LFS (hazard ratio, 9.22 [95% CI, 1.88 to 45.5; P = .006] and 10.8 [95% CI, 1.66 to 70.6; P = .01], respectively). However, none of these factors was associated with OS.

Table 2
Univariate Analyses for OS and LFS

	3-Year LFS % (range)	*P*	3-Year OS % (range)	*P*
Gender		.35		.60
Male n = 67	61.8 (50-76)		80.3 (71-91)	
Female n = 36	72.2 (58-88)		83.3 (72-96)	
Age		.70		.12
≤60 yr n = 74	69.1 (59-80)		86 (78-94)	
>60 yr n = 29	55.7 (38-81)		71.4 (56-90)	
Type of lymphoma		.22		.64
High grade n = 47	65.1 (52-80)		80.7 (70-92)	
T-NHL n = 34	66.6 (51-86)		81.9 (69-96)	
HL n = 16	46.2 (26-81)		80.2 (62-1)	
Low grade n = 6	100		100	
Treatment lines		.29		.15
≤2 n = 68	64.5 (54-77)		84.9 (76-94)	
>2 n = 35	66.7 (51-87)		75.6 (62-92)	
Status at transplant		.16		.30
Complete remission n = 56	71.4 (60-85)		83.2 (73-93)	
Partial remission n = 40	58.1 (44-76)		82.2 (71-95)	
Active disease n = 7	68.5 (10-1)		68.5 (40-1)	
Conditioning regimen		.95		.81
MAC n = 13	60.5 (38-94)		84.6 (67-1)	
RIC n = 90	66.9 (57-78)		81.4 (73-90)	
Type of donor		.57		.52
Sibling n = 43	71 (58-86		83.4 (72-95)	
MUD n = 41	64.4 (50-81)		80 (68-93)	
Alternative* n = 19	54.9 (33-90)		72.2 (51-1)	
PET pretransplant		.32		.32
<DS4 n = 61	68.4 (57-81)		85.2 (76-94)	
≥DS4 n = 20	54.5 ((36-81)		67.8 (49-93)	
PET +3 mo		<.0001		.02
<DS4 n = 73	77.7 (68-88)		88.6 (81-96)	
≥DS4 n = 20	33.3 (17-63)		64 (45-89)	
<DS4 (excluding LG) n = 67	76.2 (66-87)	<.0001	87.9 (80-96)	.04
≥DS4 (excluding LG) n = 20	33.3 (17-63)		64 (45-89)	
PET +6-9 mo		.002		.23
<DS4 n = 43	81.8 (69-96)		94.8 (82-1)	
≥DS4 n = 18	50 (31-79)		82.3 (66-1)	
<DS4 (excluding LG) n = 37	80.4 (67-96)	.005	94.4 (87-1)	.28
≥DS4 (excluding LG) n = 18	50 (31-79)		82.3 (66-1)	

LG indicates low-grade lymphoma; MAC, myeloablative conditioning; RIC, reduced-intensity conditioning; MUD, matched unrelated donor.
* Cord blood + haploidentical + 9/10 mismatched unrelated.

Age, type of lymphoma, previous number of lines of treatment, and status at transplant had no impact on LFS and OS.

CT, Lymph Node Biopsy, and Donor Lymphocyte Infusion after Transplant

Total body CT evaluation was performed for 11 of 20 and 14 of 18 patients with DS ≥ 4 at 3 months and within 6 to 9 months post-transplant, respectively. At 3 months all CTs were considered to be normal, whereas only 4 of 14 CTs were considered positive between 6 and 9 months. Lymph node biopsies guided by FDG PET-CT were performed in 7 of 20 patients at 3 months, confirming 5 early relapses, and in 4 of 18 patients at 6 to 9 months, confirming relapse in 2. Six patients received donor lymphocyte infusion between 3 and 9 months post-transplant.

DISCUSSION

The aim of this large retrospective study was to appreciate the impact on survivals of early post-transplant FDG PET-CT status in adults allografted for lymphoma. Here, DS 4 or 5 determined on FDG PET-CT at 3 months was the strongest factor associated with a lower LFS. Association with a lower OS was observed in the univariate but not multivariate analysis. This early evaluation appears to be of crucial importance because it is performed before the occurrence of relapse in most patients (all of them in this study) [21,22].

Thus, strategies that prevent relapse can be considered such as reducing or rapidly stopping immunosuppressive drugs, performing donor lymphocyte infusion to stimulate a graft-versus-lymphoma effect, or even initiating preemptive chemotherapy or immunotherapy with rituximab [13,21,22,27]. The impact of FDG PET-CT is more questionable for low-grade lymphoma because none of the 6 cases from this cohort was documented with a DS ≥ 4 at any time.

Only 1 study has previously shown lower LFS for cases with positive FDG PET-CT after allotransplant. However, the timing (median, 6 months) of these examinations did not allow prophylactic or preemptive intervention in these patients [20].

Pretransplant FDG PET-CT positivity was not predictive of survivals in this cohort, confirming previous studies [13-18]. This is likely because of the graft-versus-lymphoma effect induced by Allo-SCT, whether donor lymphocyte infusion is used or not [13-18]. Pre-allotransplant FDG PET-CT thus seems to be of little importance and should not preclude the graft. It also suggests that different FDG PET-CT time points could be more appropriate to predict relapse and survival in patients, mainly early after Allo-SCT as demonstrated here.

Surprisingly, the patients in this series were evaluated by FDG PET-CT rather than by total body CT, especially at 3 months post-transplant. Indeed, at this time only half of the patients with a positive FDG PET-CT were also evaluated by a CT. There is no clear explanation for that except that FDG PE-CT may be easier to program in our institution. However, it

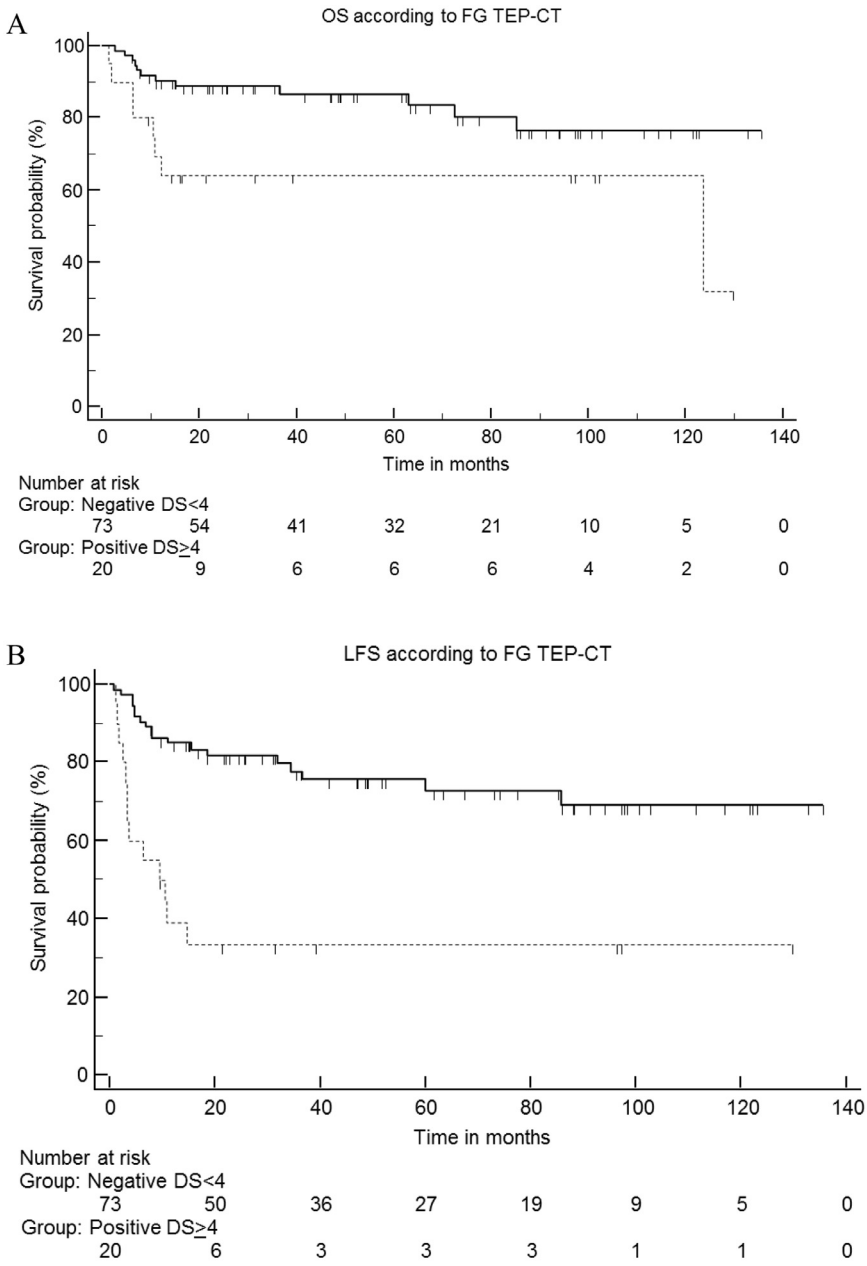

Figure 2. Comparison of OS (A) and LFS (B) between lymphoma patients with DS < 4 or ≥4 at 3 months after allotransplant.

Table 3
Multivariate Analysis for OS and LFS

	Hazard Ratio	95% CI	*P*
OS			
Age	.94	.85-1.04	.25
Previous lines of treatment	6.07	.36-101.1	.20
Status at transplant	.24	.03-1.95	.18
FDG PET CT DS			
At 3 mo	8.11	.27-243.6	.22
At 6-9 mo	3.15	.29-33.3	.33
LFS			
Type of lymphoma	.47	.15-1.41	.18
Status at transplant	.55	.13-2.33	.42
FDG PET CT DS ≥ 4			
Pretransplant	.19	.02-1.30	.09
At 3 mo	9.22	1.88-45.2	.006
At 6-9 mo	10.8	1.66-70.63	.01

seems that this did not lead to any misdiagnoses because all CTs at 3 months and 10 of 14 CTs between 6 and 9 months were considered normal. This confirms previous data from the London College Hospital where the diagnosis of 17 of 34 episodes of progression/relapse was achieved using FDG PET-CT alone, whereas CTs were judged to be negative. Moreover, no relapses were detected on CT that were not evident on FDG PET-CT in that UK study [21]. This suggests that FDG PET-CT is more appropriate to detect relapse than CT after allotransplant for lymphoma and should be prioritized for post-transplant follow-up.

Because FDG PET-CT positivity may result from infection or inflammation, it is important to consider proving histologically the recurrence of the disease in "positive" patients. Here, lymph node biopsies were performed in only a few DS ≥ 4 patients. At 3 months, however, relapse was confirmed in 5 of 7 cases. As a consequence early positivity of FDG PET-CT seems

to be highly correlated with persistence, progression, or lymphoma relapse. Therefore, documentation of relapse by biopsy should be considered for positive patients at 3 months post-transplant. However, it has to be kept in mind that, as mentioned previously, Ulaner et al. [20] reported that almost all small FDG PET-CT avid nodes (<1.5 cm) are benign and mimic malignancy, suggesting that no biopsy is needed in this context.

At 6 to 9 months post-transplant, FDG PET-CT remained associated with lower LFS for patients and should be also considered for preemptive interventions. At this time the number of biopsies performed was not sufficient to conclude on the validity of our results at that time. However, it can be proposed as of 3 months that biopsy in positive DS $\geq$ 4 patients may exclude false relapses.

Of course, our results need to be considered cautiously considering the retrospective nature of the study. Also, it would be interesting to describe the value of FDG PET-CT in a more homogeneous cohorts of patients depending on the histologic type of lymphoma.

In conclusion, FDG PET-CT positivity at 3 months appears to be highly predictive of relapse and LFS in patients with Allo-SCT for lymphoma. These results have to be validated prospectively and may help to guide strategies to prevent relapse after transplant.

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