haematologica
Journal of the Ferrata Storti Foundation

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Received: March 6, 2026.
Accepted: June 24, 2026.

Citation: Eléonore Kaphan, Hélène Kemp, Nicolas Vallet, Flore Sicre de Fontbrune, Agathe Lubineau, Marie Robin, Magalie Joris, Aliénor Xhaard, Lionel Adès, Lin-Pierre Zhao, Pierre Walczak, Régis Peffault de Latour and David Michonneau. CPX-351 before allogeneic stem cell transplantation, a real-world French experience.
Haematologica. 2026 July 2. doi: 10.3324/haematol.2026.300845 [Epub ahead of print]

CPX-351 before allogeneic stem cell transplantation, a real-world French experience

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Authors' disclosures : DM received research grant from Sanofi, Novartis and CSL Behring, and consulting fees from Incyte, Sanofi, Novartis, Jazz Pharmaceuticals, CSL Behring, Mallinckrodt. FSDF received grants or contracts from Pfizer, Novartis, Alexion, Sobi; payment or honoraria for lectures, presentations, speakers' bureaus, manuscript writing or educational events from Alexion, Sobi, Novartis,

Samsung, Pierre fabre; support for attending meetings and/or travel from Sobi, Novartis, Alexion. RPL received speaker's fees, consulting fees and research grant from Pfizer, Sobi, Novartis, Alexion. LA received grant from Celgene, AbbVie, Jazz Pharmaceutics et Takeda.

Authors' contributions

E.K., H.K., and N.V. collected the data. FSF, AL, MR, M.J., AX, LA, LPZ, , PW and RPL provided access to patients' data, E.K performed statistical analysis, E.K. and D.M. designed the study. E.K. drafted the manuscript. D.M. supervised the project. All authors critically reviewed the manuscript and approved the final version.

Data sharing statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Keywords: allogeneic hematopoietic stem cell transplantation, acute myeloid leukemia, CPX-351

CPX-351, a liposomal formulation of a fixed daunorubicin and cytarabine combination, was approved by the FDA and European Medicines Agency (EMEA) for the treatment of therapy-related acute myeloid leukemia (t-AML) and acute myeloid leukemia with myelodysplasia-related changes (AML-MRC) according to the World Health Organization (WHO) 2016 AML classification(1). A prospective randomized study demonstrated longer overall survival (9.56 vs. 5.95 months) and higher remission rate (complete remission or complete remission with incomplete neutrophil or platelet recovery 48% vs. 33%, p=0.016) for patients treated with CPX-351 compared to the standard intensive chemotherapy regimen (anthracycline and cytarabine, 3+7) (2). In a prespecified secondary analysis, 34% of patients in the CPX-351 arm and 25% in the 3+7 arm proceeded to allogeneic hematopoietic stem cell transplantation (allo-SCT). Post-transplant overall survival significantly favored CPX-351, with a hazard ratio (HR) of 0.46 (p = 0.009). It was hypothesized that this survival benefit might be attributable to deeper remissions prior to allo-SCT and/or improved pre-transplant clinical status in patients treated with CPX-351. However, as the study was not specifically designed to assess post-transplant outcomes, it did not allow for a formal evaluation of whether the survival benefit was driven by differences in pre-transplant disease status or by improved general condition and transplant-related outcomes associated with CPX-351.

To address this question, we conducted a retrospective multicenter matched case-control study with a 2:1 ratio (3+7:CPX-351), with exact matching patients based on age, sex, underlying disease (AML), conditioning intensity (Reduced Intensity Conditioning RIC or Myeloablative Conditioning MAC), disease status at the time of transplantation (complete remission or refractory), stem cell source (peripheral stem cells or bone marrow), and donor type (matched related or unrelated, mismatched unrelated or haploidentical). A secondary objective was to compare outcomes between patients treated with CPX-351 and those receiving azacitidine and venetoclax (AZA-VEN). Patients diagnosed with t-AML or AML-MRC who underwent allo-SCT between 2017 and 2023 in three French university hospitals (Paris, Amiens, and Tours) were included. Data were collected from the European Society for Blood and Marrow Transplantation (EBMT) registry. All patients had provided written informed consent for the use of their clinical and biological data for research purposes (IRB00003888 authorization 21799). This study represents the first real-world French evaluation of post–allo-SCT outcomes in patients treated frontline with CPX-351 compared with conventional 3+7 chemotherapy. The criteria used for choosing between standard induction, AZA-VEN and CPX-351 were based on local policy and physician discretion.

Conditioning regimens were categorized as myeloablative conditioning (MAC) or reduced-intensity conditioning (RIC), with MAC defined busulfan doses exceeding 6.4 mg/kg intravenously; all other regimens were considered as RIC. Acute and chronic graft versus host disease (GVHD) were scored according to international standards (3,4). The primary endpoint was post-transplant OS. Secondary endpoints included relapse-free survival (RFS), cumulative incidence (CI) of aGVHD and cGVHD, graft-versus-host disease–relapse-free survival (GRFS, defined as survival without grade III-IV aGVHD, moderate to severe cGVHD, or relapse), and non-relapse mortality (NRM). Fisher's exact test and the Mann-Whitney-Wilcoxon test were used for categorical and continuous variables, respectively. OS, RFS, NRM, and GRFS were estimated from the date of transplantation using the Kaplan-Meier method. Cumulative incidence functions were used to estimate aGVHD, cGVHD and NRM. Death and relapse were considered as competing events in the definition of GvHD cumulative incidence according to Fine and Gray model. Comparisons were performed using the log-rank test for OS, RFS and GRFS, whereas Gray's test was applied for outcome with competing events. Analyses were performed using R software (version 4.1.2) (5). A p-value < 0.05 was considered statistically significant.

During the study period, 102 patients from 60 to 73 years in Saint-Louis Hospital were referred for allo-SCT for this indication following treatment with 3+7 (n=60), CPX-351 (n=15), or azacitidine and venetoclax (AZA-VEN, n=27), among whom 62 (60.8%) ultimately underwent transplantation. The proportion of patients who did not proceed to transplantation was 45% (27/60) in the 3+7 group, 40% (6/15) in the CPX-351 group, and 25.9% (7/27) in the azacitidine-venetoclax group, with no significant difference between groups (p=0.35). A total of 95 patients from the 3 centers were included: 25 in the CPX-351 group, 50 in the control group, all of whom received induction therapy with daunorubicin (60mg/m^2/day D1-3) and cytarabine (100mg/m^2/day D1-7), and 20 AZA-VEN. Baseline characteristics were comparable between the groups **(Table 1).** At the time of transplantation, the Hematopoietic Cell Transplantation (HCT)-specific Comorbidity Index and performance status were similar between the two groups. The median follow-up was significantly longer in the control group (33.9 months; interquartile range [IQR] 9.2–47.8) compared to the CPX-351 group (18.3 months; IQR 6.5–40.8; p=0.016). It was explained by a median year of transplantation in the CPX-351 in 2021 compared to 2019 in controls (p<0.001).

Detailed post-transplant outcomes are shown in **Table 1, Supplementary Data**. The median time to neutrophil engraftment (19.0 days [IQR 16–25] vs. 22.8 days [IQR 15–25]; p=0.1) and platelet

recovery (14.0 days [IQR 11–23] vs. 35.2 days [IQR 14–36]; p=0.08) were similar within both groups (control vs CPX-351). Median hospital stay duration (31.9 days vs. 34.4 days, p=0.2) and rehospitalization rates within three months (27% vs. 36%, p=0.6) were similar within both groups.

At 12 months post-transplant, OS was similar between groups (63.5% [95%CI 47.1–85.7] for CPX-351 vs. 63.6% [95%CI 51.5–78.6] for controls; p=0.51) (**Figure 1A**). At 12 months, RFS was also comparable (59.4% [95%CI 42.8–82.5] vs. 62.7% [95%CI 50.4–78.0]; p=0.37, **Figure 1B**). Similarly, GRFS at 12 months was 49.8% (95%CI 33.3–74.7) in the CPX-351 group versus 37.5% (95% CI 26.1–53.8) in the control group, without significant differences (p=0.86) (**Figure 1C**). NRM at 12 months was comparable between groups: 18.8% (95%CI 0–36.1) in the CPX-351 group and 16.6% (95% CI, 3.9–17.7) in the matched control group (p=0.7, **Figure 1D**). Rates of aGVHD grade II-IV (**Figure 1E**) were similar (49.2% [95%CI 37.9–67.2] vs. 50.5% [95%CI 37.1–79.6]; p=0.67). At 12 months, cGVHD incidence was 32.2% (95%CI 7.5–52.4) in the CPX-351 group compared to 38.2% (95%CI 19.8–52.3) in controls, p=0.4 (**Figure 1F**). The causes of death were comparable between the two cohorts. The leading cause of death was relapse, reported in 20% of patients in the CPX-351 group and 24% in the control group (p=0.6). GVHD was the second most common cause of death, occurring in 12% and 8% of patients, respectively (p=0.7). Lastly, we compared the CPX-351 (n=25) and AZA-VEN (n=20) groups (**Supplementary Table 2**). GRFS (49.8%, 95% CI 33.3–74.7 vs 40.0%, 95% CI 23.4–68.4; p=0.64), OS (63.5%, 95% CI 47.1–85.7 vs 75.0%, 95% CI 58.2–96.6; p=0.44), NRM (18.8%, 95% CI 0–36.1 vs 10.0%, 95% CI 0–22.2; p=0.77), grade II–IV aGVHD (49.2%, 95% CI 37.9–67.2 vs 40.1%, 95% CI 32.7–65.3; p=0.47), and cGVHD (32.2%, 95% CI 7.5–52.4 vs 38.7%, 95% CI 11.5–57.5; p=0.60) were comparable between groups at 12 months. By contrast, RFS was significantly lower in the CPX-351 group (59.4%, 95% CI 42.8–82.5 vs 88.9%, 95% CI 75.5–100; p=0.02) (**Supplementary Figure 1**).

To our knowledge, this is the first real-world report detailing outcomes following allo-SCT in patients treated with CPX-351. The pivotal study demonstrated a survival advantage for patients treated with CPX-351. Two hypotheses emerged from these findings: the improved survival may be attributable either to higher rates of deeper remission prior to allo-SCT, or to better physical condition at the time of transplantation. Until now, it remained unclear whether the survival benefit occurred before allo-SCT or was primarily related to improved outcomes after transplantation.

No significant differences were observed between groups regarding key post-transplant outcomes, including OS, GRFS, NRM, and RFS. We did not observe any difference in performance status at the time of allo-SCT, hospitalization duration or rehospitalization rate.

Our findings differ somewhat from the pivotal phase III study, which enrolled aged 60 to 75 years and demonstrated a survival advantage for those treated with CPX-351 prior to transplant: the median OS after allo-SCT was not reached in the CPX-351 arm compared to 10.3 months in the 3+7 group (2,6). The improved OS observed with CPX-351 resulted from a reduction in NRM. We did not observe a survival advantage following allo-SCT when comparing the two induction regimens. One possible explanation is that the benefit of CPX-351 potentially occurring primarily before transplantation, with higher rates of complete remission. This hypothesis aligns with findings from a real-world French cohort reporting a 59% complete remission (CR/CRi) rate with CPX-351 (7). CPX-351 was associated with higher rate of undetectable minimal residual disease (MRD) in composite molecular failure ($<10^{-3}$) which has been associated with improved survival outcomes (8), suggesting that deeper remissions prior to transplant may impact long-term success. A limitation of our study is the absence of available MRD status data. Similarly, a Canadian study comparing CPX-351 to FLAG-IDA as first line treatment found no significant differences in post-transplant outcomes (9,10). Another recent study, reports similar OS at 66%, without difference between CPX-351 and 7+3 standard induction chemotherapy regarding OS, RFS, NRM and GVHD cumulative incidence (11). Lastly, a retrospective study compared Azacytidine-Venetoclax to CPX-351 and found no difference in post-transplant outcomes between the two arms (OS and RFS) (12). Our study provides detailed post-transplant outcomes with extended follow-up, with a median of 19.7 months, while previous studies had relatively shorter follow-up durations of 7.6 and 9 months, respectively (7,13).

One limitation of our study is the limited sample size in each group, thus, the absence of statistically significant differences may be due to insufficient statistical power.

Altogether, these results highlight favorable transplant outcomes in this high-risk population, with a 1 year OS of 63.5%. Still, post-transplant survival advantage for CPX-351 was not observed herein. Pre-transplant administration of CPX-351 appears feasible and was not associated with excess toxicity. Further studies specifically designed to study allo-SCT outcome are warranted to explore the best positioning of CPX-351.

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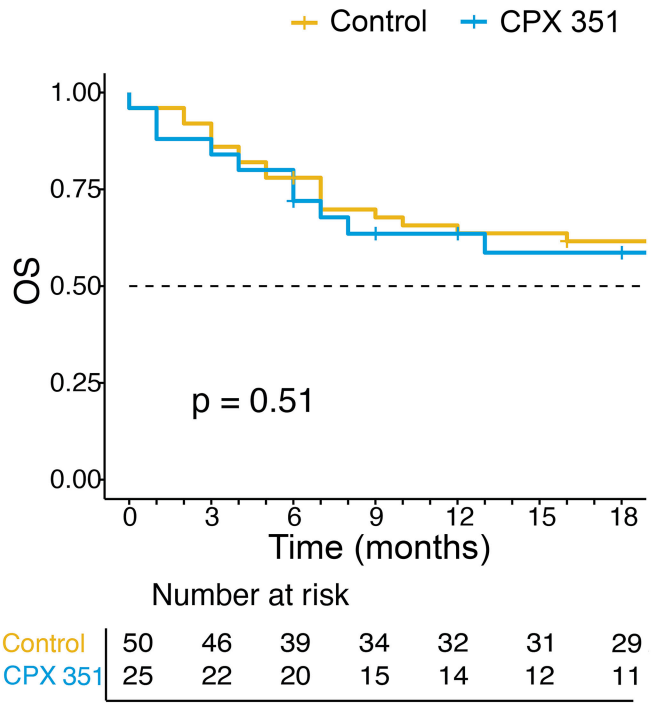
	3+7 **N=50**	**CPX-351** **N=25**	**p**
Mean age at diagnosis in years (IQR)	61.5 (50-67)	61.0 (50-67)	0.9
Mean year of allo-SCT (IQR)	2019 (2017-2021)	2021 (2020-2022)	<0.001
Median time from diagnosis to allo-SCT in days (96% CI)	173.7 (147.2-220.2)	170.8 (145.8-195.7)	0.9
Male recipient sex, n (%)	35 (70.0)	17 (68.0)	0.9
Male donor sex, n (%) F in M	29 (58.0) 11/50	18 (72.0) 7/25	0.5
Donor age in years (IQR)	34 (24-47)	34 (24-47)	1
Genetic risk by ELN 2017 Favorable Intermediate Unfavorable	 5 (10.0) 17 (34.0) 28 (56.0)	 1 (4.0) 6 (24.0) 18 (68.0)	0.3
Genetic risk by ELN 2022 Favorable Intermediate Unfavorable	 2 (4.0) 18 (36.0) 30 (60.0)	 1 (4.0) 4 (16.0) 20 (80.0)	0.4
Treatment: Single induction Re-induction Number of consolidations, median, IQR	 34 (68) 16 (32) 2 (1-2)	 21 (84) 4 (16) 1 (1-2)	0.1
Disease status at SCT, n (%): CR Refractory	 46 (92.0) 4 (8.0)	 21 (84.0) 4 (16.0)	0.3
HCT-CI score at diagnosis, n (%) 0 1-2 ≥3	 21 (42.0) 14 (28.0) 15 (30.0)	 6 (24.0) 5 (20.0) 14 (56.0)	0.1

ECOG at transplant, n (%)			0.7
NA	16 (32.0)	7 (28.0)	
0	18 (36.0)	7 (28.0)	
1	12 (24.0)	9 (36.0)	
2	3 (6.0)	1 (4.0)	
3	0 (0.0)	1 (4.0)	
4	1 (2.0)	0 (0.0)	
Conditioning Regimen, n (%)			0.7
MAC	4 (8.0)	1 (4.0)	
RIC	46 (92.0)	24 (96.0)	
ATG, n (%)	38 (76.0)	17 (68.0)	0.6
Donor type, n (%)			0.9
Matched related	11 (22.0)	4 (16.0)	
Matched unrelated	29 (58.0)	15 (60.0)	
Haploidentical	9 (18.0)	4 (16.0)	
Mismatched unrelated	1 (2.0)	2 (8.0)	
Stem cell source, n (%)			1.0
Bone marrow	2 (4.0)	1 (4.0)	
Peripheral blood	48 (96.0)	24 (96.0)	
GVHD prophylaxis, n (%)			0.1
CNI and MMF	30 (60.0)	17 (68.0)	
CNI and MTX	11 (22.0)	2 (8.0)	
CNI and MMF and PTCy	9 (18.0)	6 (24.0)	

Table 1. Description of the CPX-351 and control groups at allogeneic stem cell transplantation (allo-SCT). CR: complete response, D: donor, R: recipient, BM: bone marrow, PSC: peripheral stem cell, GVHD: graft versus host disease, MAC: myeloablative conditioning, RIC: reduced intensity conditioning, CNI: calcineurin inhibitor, MMF: mycophenolate mofetil, MTX: methotrexate, PTCY: post-transplant cyclophosphamide, ATG: anti-thymoglobulin, NA: not available, IQR: interquartile range, HCT-CI: Hematopoietic Cell Transplantation-specific Comorbidity Index

Figure legends

Figure 1. Main outcomes after allogeneic stem cell transplantation, comparison between CPX 351 and control groups. (A) Kaplan Meier (KM) curve describing overall survival, (B) KM curve showing relapse free survival, (C) KM curve reporting graft versus host disease relapse free survival (GRFS), (D) cumulative incidence (CI) curve of non-relapse mortality (NRM), (E) CI of grade II-III-IV of acute graft versus host disease (aGVHD) and (F) for chronic graft versus host disease (cGVHD).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CPX 351
OS
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0.75
0.50
0.25
0.00
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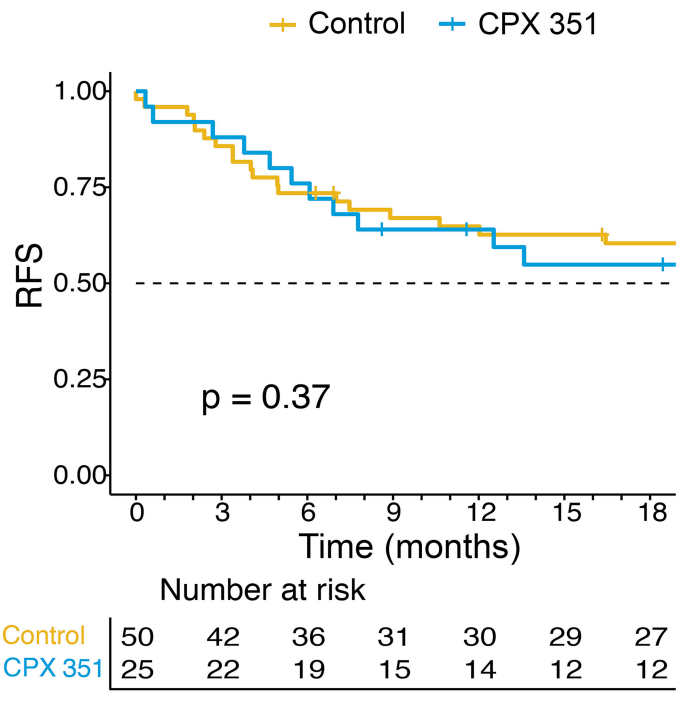
0 3 6 9 12 15 18
Time (months)
Number at risk
Control 50 46 39 34 32 31 29
CPX 351 25 22 20 15 14 12 11


Control
CPX 351
RFS
1.00
0.75
0.50
0.25
0.00
p = 0.37
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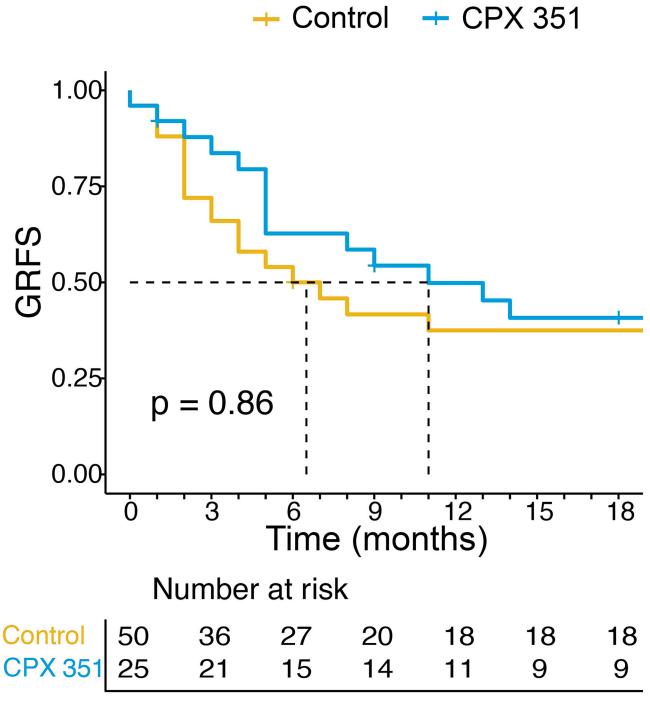
Time (months)
Number at risk
Control 50 42 36 31 30 29 27
CPX 351 25 22 19 15 14 12 12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GRFS
1.00
0.75
0.50
0.25
0.00
p = 0.86
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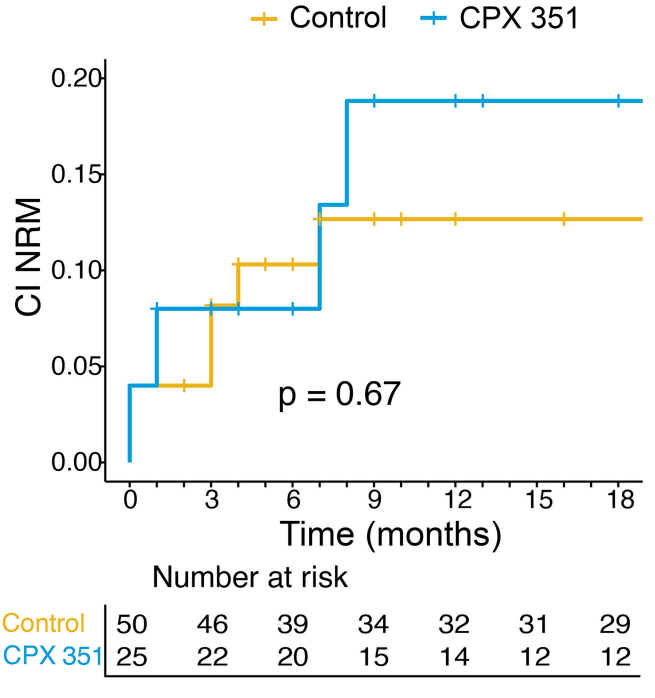
Time (months)
Number at risk
Control 50 36 27 20 18 18 18
CPX 351 25 21 15 14 11 9 9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CI NRM
0.20
0.15
0.10
0.05
0.00
p = 0.67
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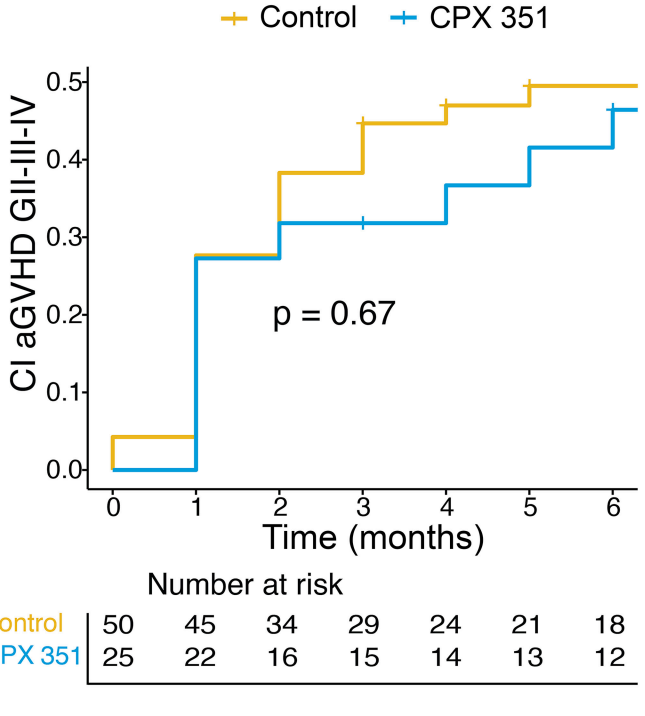
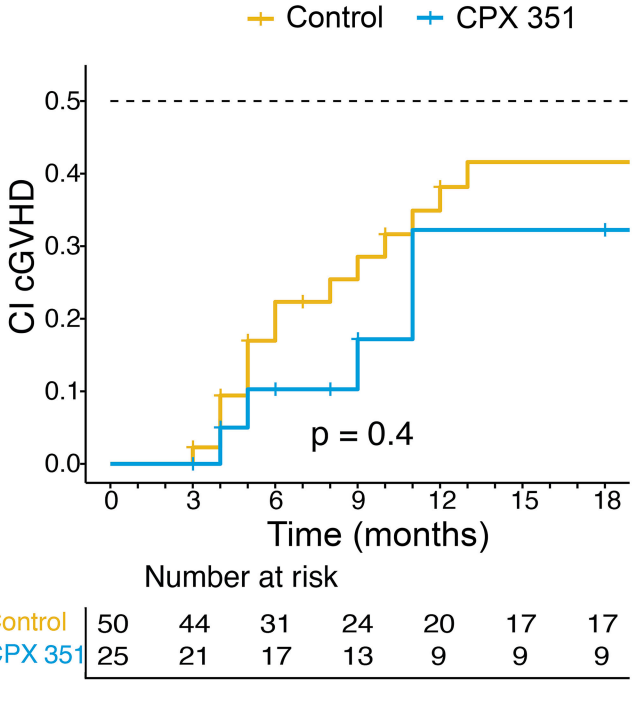
Time (months)
Number at risk
Control 50 46 39 34 32 31 29
CPX 351 25 22 20 15 14 12 12


Control
CPX 351
CI aGVHD GII-III-IV
0.5
0.4
0.3
0.2
0.1
0.0
p = 0.67
0 1 2 3 4 5 6
Time (months)
Number at risk
Control 50 45 34 29 24 21 18
CPX 351 25 22 16 15 14 13 12


Control
CPX 351
CI cGVHD
0.5
0.4
0.3
0.2
0.1
0.0
p = 0.4
0 3 6 9 12 15 18
Time (months)
Number at risk
Control 50 44 31 24 20 17 17
CPX 351 25 21 17 13 9 9 9

Supplementary Data

	3+7 N=50	CPX-351 N=25	p
Engraftment, n (%):			
Neutrophils	48 (96.0)	22 (96.0)	1.0
Platelets	48 (96.0)	21 (94.0)	0.6
Hospital discharge, n (%):	48 (96.0)	25 (100)	0.4
Early death	1 (2.0)	3 (12.0)	
Home	45 (90.0)	21 (84.0)	
Rehabilitation care	2 (4.0)	1 (4.0)	
Rehospitalization before D100, n (%)	13 (27.0)	9 (36.0)	0.1
FLT3 inhibitor maintenance, n (%)	15 (30)	7 (28)	0.9
Acute GVHD, n (%)	23 (48.9)	10 (45.5)	1.0
Maximal grade, n (%)			0.4
I	6 (26.1)	1 (10.0)	
II	8 (34.8)	6 (60.0)	
III	6 (26.1)	1 (10.0)	
IV	3 (13.0)	2 (20.0)	
Corticosteroids sensitivity, n (%)	11 (47.8)	5 (50.0)	0.9
Chronic GVHD, n (%)	18 (59.1)	6 (24.0)	0.5
Score NIH, n (%)			0.5
Mild	8 (44.4)	1 (16.7)	
Moderate	7 (38.9)	4 (66.7)	
Severe	3 (16.7)	1 (16.7)	
Response to first line therapy for cGVHD, n (%)	/18	/6	0.6
CR	6 (33.3)	4 (66.7)	
PR	1 (5.6)	0 (0)	
Refractory	8 (44.4)	2 (33.3)	
NA	3 (16.7)	0 (0)	

Supp Table 1. Outcomes after allogeneic stem cell transplantation, comparison between CPX-351 and control groups. GVHD: graft versus host disease, cGVHD: chronic GVHD, CR: complete response, PR: partial response, SD: stable disease, NA: not available

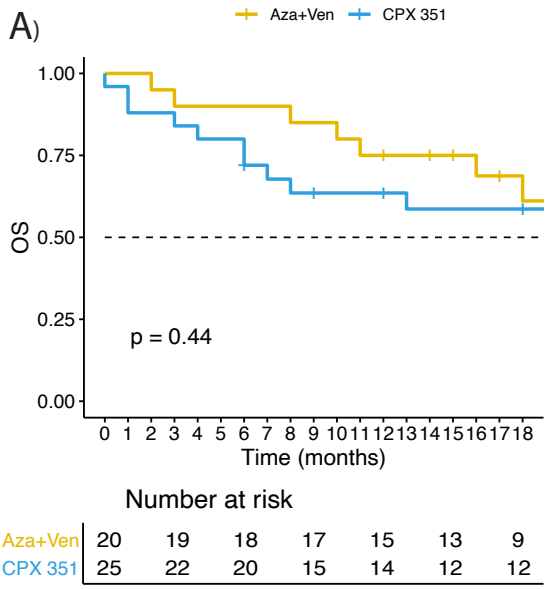
	Aza-Ven N=20	**CPX-351 N=25**	**p**
Mean age at diagnosis in years (IQR)	69 (64-71)	61.0 (50-67)	0.003
Median year of allo-SCT (IQR)	2022 (2021-2024)	2021 (2020-2022)	0.001
Median time from diagnosis to allo-SCT in days (96% CI)	147.5 (117.3-192.3)	170.8 (145.8-195.7)	0.7
Male recipient sex, n (%)	10 (50.0)	17 (68.0)	0.2
Male donor sex, n (%) F in M	15 (75.0) 5/20	18 (72.0) 7/25	0.8
Donor age in years (IQR)	38 (29-46)	34 (24-47)	0.6
Genetic risk by ELN 2017 Favorable Intermediate Unfavorable	 0 (0.0) 8 (40.0) 12 (60.0)	 1 (4.0) 6 (24.0) 18 (68.0)	0.5
Genetic risk by ELN 2022 Favorable Intermediate Unfavorable	 0 (0.0) 2 (10.0) 18 (90.0)	 1 (4.0) 4 (16.0) 20 (80.0)	0.4
Treatment: Single induction Re-induction Number of consolidations, median, IQR Number of cycles, median, IQR	 2.5 (2-3.3)	 21 (84) 4 (16) 1 (1-2)	NA
Disease status at SCT, n (%): CR Refractory	 19 (95.0) 1 (5.0)	 21 (84.0) 4 (16.0)	0.4
HCT-CI score at diagnosis, n (%) 0 1-2 ≥3	 7 (35.0) 10 (50.0) 3 (15.0)	 6 (24.0) 5 (20.0) 14 (56.0)	0.06

ECOG at transplant, n (%) NA 0 1 2 3 4	 0 (0.0) 2 (10.0) 14 (70.0) 4 (20.0) 0 (0.0) 0 (0.0)	 7 (28.0) 7 (28.0) 9 (36.0) 1 (4.0) 1 (4.0) 0 (0.0)	0.7
Conditioning Regimen, n (%) MAC RIC	 1 (5.0) 19 (95.0)	 1 (4.0) 24 (96.0)	1.0
ATG, n (%)	11 (55.0)	17 (68.0)	0.4
Donor type, n (%) Matched related Matched unrelated Haploidentical Mismatched unrelated	 2 (10.0) 10 (50.0) 5 (25.0) 3 (15.0)	 4 (16.0) 15 (60.0) 4 (16.0) 2 (8.0)	0.7
Stem cell source, n (%) Bone marrow Peripheral blood	 0 (0.0) 20 (100.0)	 1 (4.0) 24 (96.0)	1.0
Engraftment, n (%): Neutrophils Platelets	 19 (95.0) 20 (100.0)	 22 (96.0) 21 (94.0)	 1.0 1.0
Hospital discharge, n (%): Early death Home Rehabilitation care	 1 (5.0) 18 (90.0) 1 (5.0)	 3 (12.0) 21 (84.0) 1 (4.0)	0.07
Rehospitalization before D100, n (%)	6 (30.0)	9 (36.0)	0.6
FLT3 inhibitor maintenance, n (%)	3 (15)	15 (30)	0.3

Supp Table 2. Description of the CPX-351 and AZA+VEN at allogeneic stem cell transplantation (allo-SCT). CR: complete response, D: donor, R: recipient, BM: bone marrow, PSC: peripheral stem

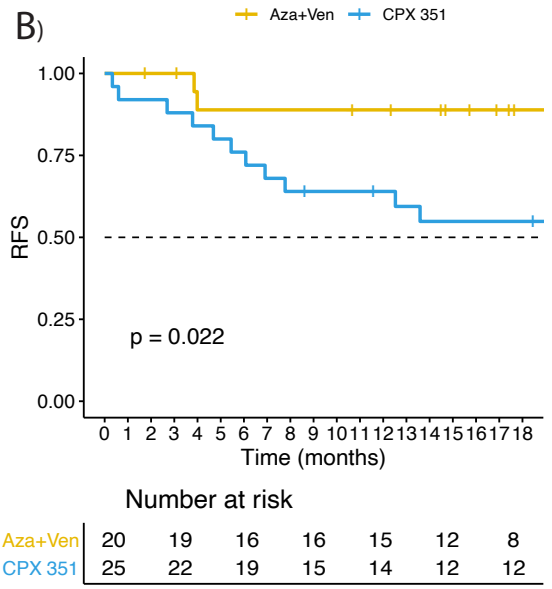
cell, GVHD: graft versus host disease, MAC: myeloablative conditioning, RIC: reduced intensity conditioning, CNI: calcineurin inhibitor, MMF: mycophenolate mofetil, MTX: methotrexate, PTCY: post-transplant cyclophosphamide, ATG: anti-thymoglobulin, NA: not available, IQR: interquartile range, HCT-CI: Hematopoietic Cell Transplantation-specific Comorbidity Index

Supp Figure 1 . Main outcomes after allogeneic stem cell transplantation, comparison between CPX 351 and Aza-Ven. (A) Kaplan Meier (KM) curve describing overall survival, (B) KM curve showing relapse free survival, (C) KM curve reporting graft versus host disease relapse free survival (GRFS), (D) cumulative incidence (CI) curve of non-relapse mortality (NRM), (E) CI of grade II-III-IV of acute graft versus host disease (aGVHD) and (F) for chronic graft versus host disease (cGVHD).



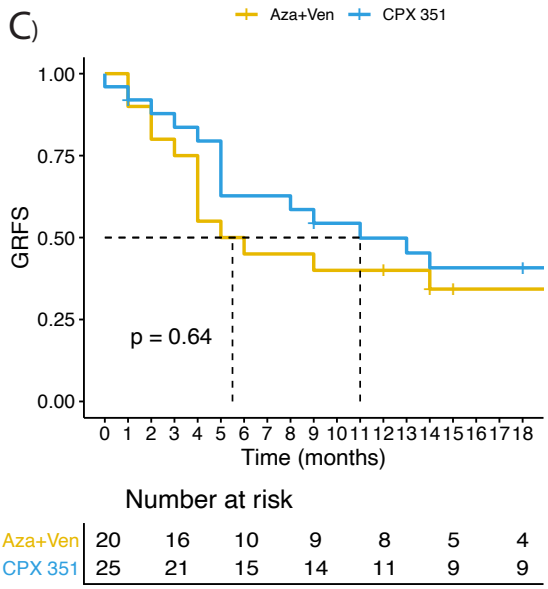
Number at risk

Aza+Ven	20	19	18	17	15	13	9
CPX 351	25	22	20	15	14	12	12



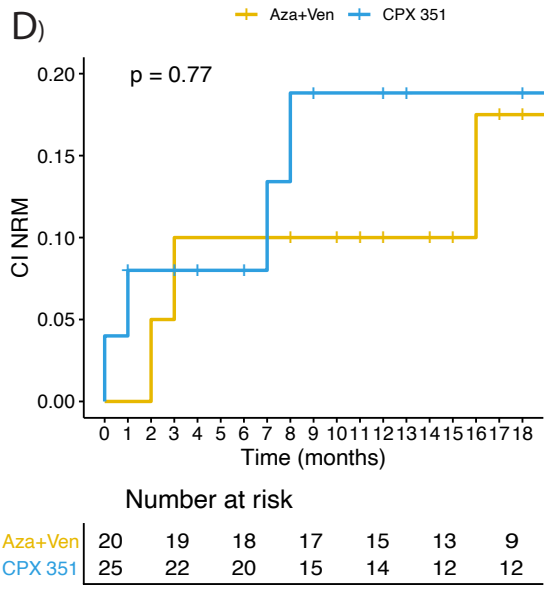
Number at risk

Aza+Ven	20	19	16	16	15	12	8
CPX 351	25	22	19	15	14	12	12



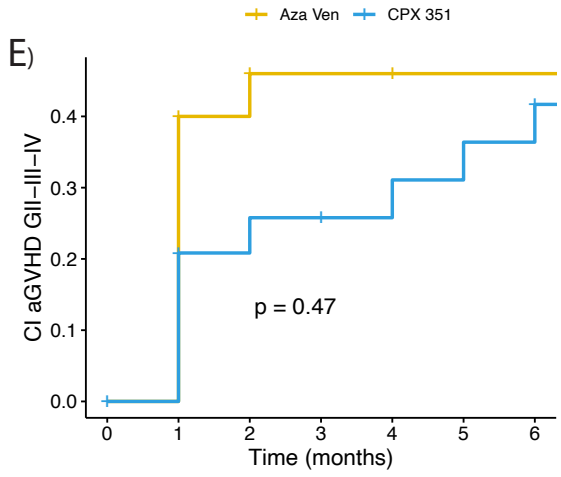
Number at risk

Aza+Ven	20	16	10	9	8	5	4
CPX 351	25	21	15	14	11	9	9



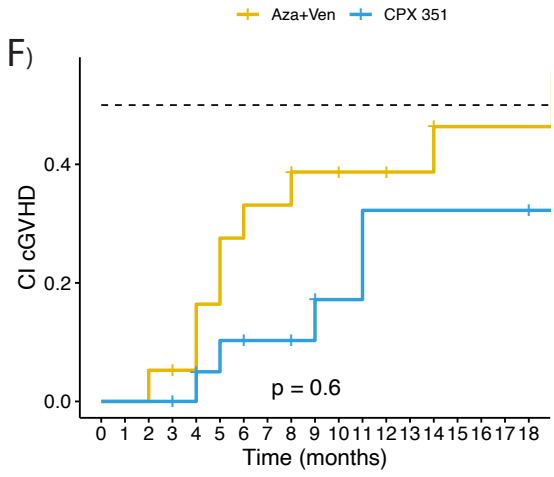
Number at risk

Aza+Ven	20	19	18	17	15	13	9
CPX 351	25	22	20	15	14	12	12



Number at risk

AzaVen	20	20	10	7	7	6	6
CPX351	25	24	16	15	14	13	12



Number at risk

Aza+Ven	20	18	13	10	9	6	6
CPX351	25	21	17	13	9	9	9