Received: 15 January 2024 | Accepted: 19 February 2024

DOI: 10.1111/bjh.19372

BJHaem
BRITISH JOURNAL OF HAEMATOLOGY

SHORT REPORT

Transplantation

First complete remission favours haploidentical haematopoietic stem cell transplantation with post-transplant cyclophosphamide over cord blood transplantation in acute lymphoblastic leukaemia

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Funding information
Ministry of Education, Culture, Sports, Science and Technology

Summary
To assess the benefits of HLA-haploidentical haematopoietic stem cell transplantation using post-transplant cyclophosphamide (PTCy-haplo) relative to those of umbilical cord blood (UCB) transplantation in acute lymphoblastic leukaemia (ALL), we analysed 1999 patients (PTCy-haplo, 330; UCB, 1669), using the nationwide Japanese registry. PTCy-haplo was associated with a significantly higher relapse rate, but lower non-relapse mortality, which results in overall survival and disease-free survival, comparable to those of UCB. Among patients in CR1, PTCy-haplo showed a significantly higher survival than UCB regardless of the $CD34^+$ cell dose. Our findings provide valuable insights into the donor selection algorithm in allogeneic HSCT for adult patients with ALL.

KEYWORDS
acute lymphoblastic leukaemia, HLA-haploidentical stem cell transplantation using post-transplant cyclophosphamide, umbilical cord blood

In the absence of HLA-matched donors, HLA-haploidentical haematopoietic stem cell transplantation (HSCT) using post-transplant cyclophosphamide (PTCy-haplo) and umbilical cord blood (UCB) transplantation are alternatives for HSCT.[1–3] Previous studies suggested that PTCy-haplo offers the advantage of lower non-relapse mortality (NRM) than UCB, but raises concerns about diminished graft-versus-leukaemia (GVL) effects and increased risk of post-transplant relapse.[4] Given that post-transplant relapse is still common in adult lymphoblastic leukaemia (ALL),[5] an ALL-specific comparison between PTCy-haplo and UCB is required. However, pertinent data are still limited.[6–8] Here, we retrospectively analysed a nationwide Japanese cohort to (1) compare the outcomes of adult patients with ALL between PTCy-haplo and UCB transplantation; (2) identify subgroups who are most likely to benefit from PTCy-haplo.

PATIENTS AND METHODS

Data on adult patients (age ≥16 years) with ALL who underwent PTCy-haplo or single-unit UCB transplantation

For Affiliation refer page on 1917

TABLE 1 Patient characteristics.

	Total (*N* = 1999)	PTCy-haplo (*N* = 330)	UCB (*N* = 1669)	*p*-Value
Patient age, years				
Median (range)	45 (16–74)	44.5 (16–73)	45 (16–74)	0.033*
<50	1186 (59.3%)	194 (58.8%)	992 (59.4%)	0.854
≥50	813 (40.7%)	136 (41.2%)	677 (40.6%)	
Patient sex				0.009*
Male	1085 (54.3%)	201 (60.9%)	884 (53.0%)	
Female	913 (45.7%)	129 (39.1%)	784 (47.0%)	
ECOG PS				0.019*
0–1	1760 (88.0%)	303 (91.8%)	1457 (87.3%)	
2–4	232 (11.6%)	26 (7.9%)	206 (12.3%)	
HCT-CI				0.500
0–2	1682 (84.1%)	281 (85.2%)	1401 (83.9%)	
≥3	302 (15.1%)	45 (13.6%)	257 (15.4%)	
CMV-Ab				0.631
Negative	345 (17.3%)	53 (16.1%)	292 (17.5%)	
Positive	1602 (80.1%)	266 (80.6%)	1336 (80.0%)	
Phenotype				<0.001*
B cell	1430 (71.5%)	254 (77.0%)	1176 (70.5%)	
T cell	241 (12.1%)	39 (11.8%)	202 (12.1%)	
Other	93 (4.7%)	2 (0.6%)	91 (5.5%)	
Ph chromosome				0.118
Negative	1271 (63.6%)	197 (59.7%)	1074 (64.3%)	
Positive	728 (36.4%)	133 (40.3%)	595 (35.7%)	
Disease status				0.051
CR1	980 (49.0%)	166 (50.3%)	814 (48.8%)	
CR2	341 (17.1%)	69 (20.9%)	272 (16.3%)	
≥3 CR/non-CR	445 (22.3%)	61 (18.5%)	384 (23.0%)	
rDRI				0.069
Intermediate	980 (49.0%)	166 (50.3%)	814 (48.8%)	
High	436 (21.8%)	84 (25.5%)	352 (21.1%)	
Very high	350 (17.5%)	46 (13.9%)	304 (18.2%)	
Number of transplants				0.089
1st	1524 (76.2%)	264 (80.0%)	1260 (75.5%)	
≥2nd	475 (23.8%)	66 (20.0%)	409 (24.5%)	
Time from diagnosis to transplantation, months				
Median (range)	7.8 (0.7–219.7)	7.8 (1.9–213.2)	7.7 (0.7–219.7)	0.605
≤3	46 (2.3%)	4 (1.2%)	42 (2.5%)	0.273
3–6	641 (32.1%)	101 (30.6%)	540 (32.4%)	
≥6	1311 (65.6%)	225 (68.2%)	1086 (65.1%)	
$CD34^+$ cell dose, 10^6/kg (PTCy-haplo),[a] 10^5/kg (UCB)				
Median (range)	-	4.5 (1.1–17.6)	0.85 (0.11–19.2)	-
Sex mismatch				0.804
Matched	988 (49.4%)	165 (50.0%)	823 (49.3%)	
Male to female	462 (23.1%)	76 (23.0%)	386 (23.1%)	
Female to male	497 (24.9%)	89 (27.0%)	408 (24.4%)	

TABLE 1 (Continued)

	Total (*N* = 1999)	PTCy-haplo (*N* = 330)	UCB (*N* = 1669)	*p*-Value
ABO mismatch				<0.001*
Matched	694 (34.7%)	178 (53.9%)	516 (30.9%)	
Minor mismatch	499 (25.0%)	57 (17.3%)	442 (26.5%)	
Major mismatch	504 (25.2%)	64 (19.4%)	440 (26.4%)	
Major–minor mismatch	299 (15.0%)	30 (9.1%)	269 (16.1%)	
Conditioning				0.165
Myeloablative	1082 (54.1%)	167 (50.6%)	915 (54.8%)	
Reduced intensity	916 (45.8%)	163 (49.4%)	753 (45.1%)	
TBI				0.229
No	403 (20.2%)	58 (17.6%)	345 (20.7%)	
Yes	1596 (79.8%)	272 (82.4%)	1324 (79.3%)	
Years of transplant				<0.001*
2013–2017	937 (46.9%)	77 (23.3%)	860 (51.5%)	
2018–2021	1062 (53.1%)	253 (76.7%)	809 (48.5%)	

Abbreviations: Ab, antibody; CMV, cytomegalovirus; CR, complete remission; ECOG PS, Eastern Cooperative Oncology Group Performance Status Scale; GVHD, graft-versus-host disease; HCT-CI, haematopoietic cell transplantation-specific comorbidity index; Ph, Philadelphia; PTCy-haplo, HLA-haploidentical transplantation using post-transplant cyclophosphamide; rDRI, refined disease risk index; TBI, total body irradiation; UCB, umbilical cord blood.

[a]PTCy-haplo recipients using peripheral blood stem cells (PBSCs) as grafts ($n = 315$, 95.5%).

*$p < 0.05$.

between 2013 and 2021 were obtained through the Transplant Registry Unified Management Program (TRUMP).[9,10] The study was approved by the Institutional Review Board of Kyoto University Hospital and was conducted in accordance with the Declaration of Helsinki. Definitions of variables and statistical methods are described in the Supporting Information.

RESULTS

One thousand nine hundred and ninety-nine patients (PTCy-haplo, 330; UCB, 1699) were eligible for analysis. Baseline demographics are summarized in Table 1 and Table S1. Median age at transplantation was 44.5 years (range, 16–73) in the PTCy-haplo group and 45 years (range, 16–74) in the UCB group. Disease status at transplantation was first complete remission (CR1) in 49.0% of the whole cohort, and no significant differences were observed between the groups. Median $CD34^+$ cell dose was 4.5×10^6/kg in PTCy-haplo recipients using peripheral blood stem cells as grafts, and 0.85×10^5/kg in UCB recipients. Proportions of those who received myeloablative conditioning were comparable between the groups.

Respective 3-year overall survival (OS) and disease-free survival (DFS) rates were 54.1% and 49.7% in the PTCy-haplo group and 52.3% and 47.1% in the UCB group (Figure S1A,B). Multivariate analyses revealed that OS (adjusted hazard ratio [aHR], 0.910; 95% confidence interval [CI], 0.718–1.154; $p = 0.437$) and DFS (aHR, 1.036; 95% CI, 0.831–1.293; $p = 0.751$) were similar between the groups (Tables S2 and S3). PTCy-haplo recipients had a significantly higher cumulative incidence of relapse (32.2% vs. 26.4% at 3 years; aHR, 1.525; 95% CI, 1.139–2.043; $p = 0.005$), compared with UCB recipients (Figure S1C). Indeed, relapse death accounted for a significantly larger proportion of total death in the PTCy-haplo group than in the UCB group (Table S4). By contrast, NRM was significantly lower among PTCy-haplo recipients than UCB recipients (18.1% vs. 25.6% at 3 years; aHR, 0.653; 95% CI, 0.463–0.922; $p = 0.015$) (Figure S1D). In the propensity-matched cohort (Table S5), the PTCy-haplo group had similar 3-year OS and DFS, as well as a significantly higher relapse rate, and lower NRM (Figure S2A–D).

Then, we analysed post-transplant engraftment and complications. Significantly more robust engraftments were observed in the PTCy-haplo group (Figure S3A,B). Cumulative incidence of viral, fungal or bacterial infection at day 100 after transplantation was significantly lower in the PTCy-haplo group (Figure S3C–I), and death caused by graft failure or infection accounted for a smaller proportion of NRM in the PTCy-haplo group (Table S4). For GVHD, there was no significant difference in cumulative incidence of acute, or chronic GVHD between the two groups (Figure S4A–D). Incidence of TMA or VOD/SOS was similar (Figure S3J,K). These results suggest that fewer infections without an increase in GVHD or other complications lead to lower NRM among PTCy-haplo recipients.

Next, in order to identify subgroup of patients who benefit more from PTCy-haplo than UCB, we performed subgroup analysis (Figure S5). Significantly more favourable OS was observed in PTCy-haplo than in UCB in the patient

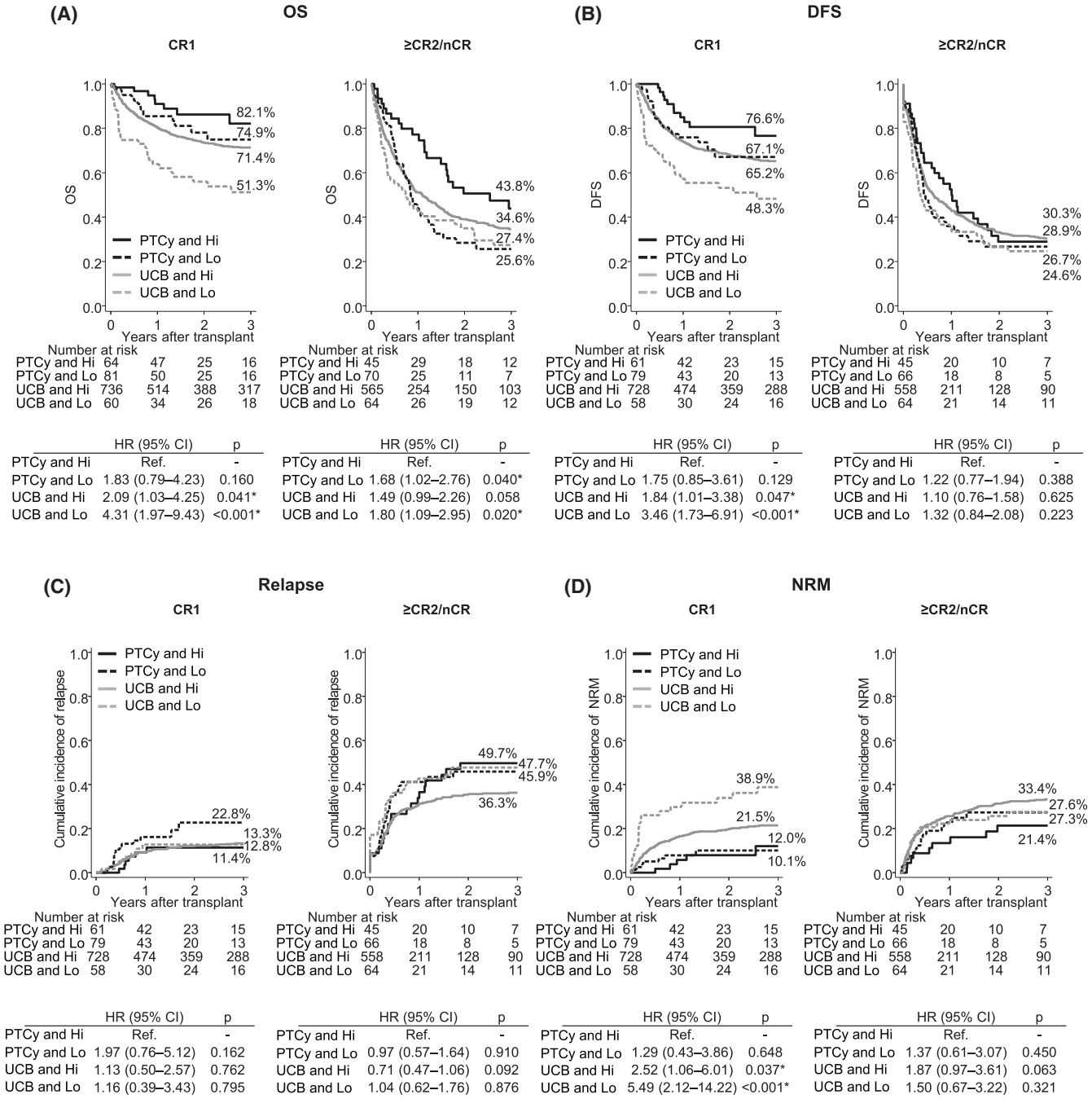

FIGURE 1 Comparison of outcomes between HLA-haploidentical stem cell transplantation using post-transplant cyclophosphamide (PTCy-haplo) and umbilical cord blood transplantation (UCB), according to disease status at transplant and $CD34^+$ cell doses in the whole cohort. Comparisons between groups among those transplanted at first complete remission (CR1) in left panels and at ≥2nd CR or non-CR in the right panels. (A) Overall survival (OS). (B) Disease-free survival (DFS). (C) Cumulative incidence of relapse. (D) Cumulative incidence of non-relapse mortality (NRM). Hazard ratios (HRs) and *p* values were calculated using the Cox proportional hazards model (A, B) and Fine and Gray's tests (C, D). "*" Indicates $p < 0.05$.

subgroup with CR1 at transplantation (HR, 0.662; 95% CI, 0.452–0.969; $p = 0.034$), and in patients with transplanted $CD34^+$ cell doses ≥ the median value (HR, 0.641; 95% CI, 0.467–0.879; $p = 0.006$).

In patients with CR1 at transplantation, PTCy-haplo was associated with significantly better 3-year OS (76.0% vs. 69.5%; $p = 0.034$), as well as a similar cumulative incidence of relapse (17.0% vs. 13.7%, $p = 0.279$) and a significantly lower NRM (12.8% vs. 22.6%, $p = 0.003$), compared to UCB (Figure S6A–D). After adjusting for patient background in CR1, the results remained consistent with these findings (Figure S7A–D; Table S6), suggesting that the low NRM outweighs concerns of relapse among patients in CR1. In contrast, PTCy-haplo offered no advantage to patients with CR2

or more advanced-stage disease (Figures S6A–D and S7A–D; Table S7).

Because subgroup analysis suggested that PTCy-haplo has better OS among patients with sufficient $CD34^+$ cell doses, we evaluated effects of $CD34^+$ cell dose, which were broadly distributed in both groups (Figure S8A,B). OS improved with higher $CD34^+$ cell doses, even above the median in PTCy-haplo recipients, but not in UCB recipients (Figure S8C,D). Indeed, when patients were divided into four groups according to $CD34^+$ cell dose, PTCy-haplo with $CD34^+$ cell doses $\geq 5 \times 10^6$/kg showed higher OS and DFS than those with lower $CD34^+$ cell dose (Figure S9A,B). In PTCy-haplo recipients, lower $CD34^+$ doses were associated with a tendency towards increased relapse or NRM (Figure S9C,D).

Next, we compared post-transplant outcomes of PTCy-haplo and UCB in combination with disease status at transplantation and $CD34^+$ cell dose (cut-off, 5×10^6/kg for PTCy-haplo and 0.5×10^5/kg for UCB). For patients transplanted in CR1, in both the unadjusted and propensity score-matched cohort, the PTCy-haplo group had better OS and DFS than the UCB group, regardless of $CD34^+$ cell dose, as well as lower NRM and a comparable relapse rate (Figure 1A–D; Figure S10A–D). In particular, the PTCy and high group had the highest OS and DFS among the groups. In patients with more advanced-stage disease, benefits of PTCy-haplo over UCB were not consistently observed. The PTCy and Low group exhibited a trend towards a worse OS than UCB groups.

DISCUSSION

The present study revealed two major findings for adult ALL patients. (1) PTCy-haplo was associated with a significantly higher relapse rate, but lower NRM, which results in comparable OS and DFS, compared to UCB. (2) In patients in CR1, PTCy-haplo showed a significantly higher survival than UCB regardless of the $CD34^+$ cell dose.

First, we showed that PTCy-haplo recipients had OS and DFS similar to those of UCB recipients as a whole. Since, in this study, relapse rate was higher among the PTCy-haplo recipients, which is consistent with previous studies,[7,8,11] approaches to reduce relapse among PTCy-haplo recipients should be further investigated.[12] Also, we clearly showed that the lower NRM in the PTCy-haplo group derives from lower risk of infectious complications than in UCB transplantation.

Our second major finding was that, in ALL patients in CR1, the PTCy-haplo group showed significantly better OS, as well as reduced NRM and equivalent relapse, compared to UCB. It was reported that UCB reduces post-transplant relapse by exerting potent GVL effects.[13] As patients with CR1 have a lower risk of relapse compared with those with more advanced stages,[14] our results suggest that the disadvantage of PTCy-haplo over UCB in terms of increased risk of relapse may be small in this patient subgroup.

We showed that PTCy-haplo is superior to UCB in patients with CR1, regardless of $CD34^+$ cell dose. However, in patients with CR2 or more advanced-stage disease, PTCy-haplo recipients with low $CD34^+$ cell dose had a trend towards poorer OS than UCB. These results can optimize donor selection algorithms for adult ALL patients without HLA-matched donors. For patients at CR1, HLA-haploidentical donors are preferred over UCB, even if a suitable cord blood unit can be obtained. By contrast, for patients at CR2 or more advanced stage, advantages of PTCy-haplo over UCB vary depending on the $CD34^+$ cell dose. Optimization of $CD34^+$ cell dose in PTCy-haplo transplantation is needed.[15]

The present study has several limitations. Since it was a retrospective, multicentre registry study, patient pretransplant characteristics cannot be completely adjusted between the PTCy-haplo and UCB groups, even with multivariate analysis or propensity score matching. The majority of the cohort consisted of cases from real-world settings, but cases reported in clinical studies were included.[3,7] Thus, our findings require further validation. As this study included exploratory subgroup analyses, direct comparisons should be performed in a more specific manner to validate our findings. The potential impact of donor unavailability in PTCy-haplo and cord blood units on the donor selection process was not adjusted in this study. In this multivariate analysis, no effect of transplant year on OS was detected. However, considering that treatment options for recurrence and complications have increased over time, the influence of transplant year should continue to be monitored.

In conclusion, while PTCy-haplo and UCB are suitable donor sources for adult ALL patients without HLA-matched donors, in patients with CR1, selection of PTCy-haplo rather than UCB may improve post-transplant prognosis. Our results should help to improve donor selection algorithms in HSCT for adult ALL patients.

AUTHOR CONTRIBUTIONS

TJ, TU, Y Akahoshi, TK and Y Arai designed the study; TJ and Y Arai performed the statistical analysis; TJ, TU, Y Akahoshi, TK and Y Arai interpreted the data. TJ and Y Arai wrote the manuscript. NU, MT, HN, ND, SO, MS, HO, YM, NT, TN, NH and YK provided the patient data. YK, TI and Y Atsuta collected patient data, and all authors reviewed and provided critiques on the manuscript.

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ACKNOWLEDGEMENTS

The authors thank all physicians and data managers at centres who contributed valuable data on transplantation to the Japanese Society Transplantation and Cellular Therapy (JSTCT).

FUNDING INFORMATION

This work was supported in part by research funding from the Program for Development of Next-generation Leading Scientists with Global Insight (L-INSIGHT), sponsored by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) awarded to Y. Arai.

CONFLICT OF INTEREST STATEMENT

The authors declare no competing financial and non-financial interests.

DATA AVAILABILITY STATEMENT

Data used in this study are not publicly available due to ethical restrictions imposed by the limitations of recipient/donor consent.

ETHICS STATEMENT

The study was planned by the Adult ALL Working Group of the JSTCT, approved by the data management committees of JSTCT and by the Institutional Review Board of Kyoto University Hospital, and was conducted in accordance with the Declaration of Helsinki.

PATIENT CONSENT STATEMENT

Written informed consent was obtained from all patients.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Jo T, Ueda T, Akahoshi Y, Kondo T, Uchida N, Tanaka M, et al. First complete remission favours haploidentical haematopoietic stem cell transplantation with post-transplant cyclophosphamide over cord blood transplantation in acute lymphoblastic leukaemia. Br J Haematol. 2024;204(5):1913–1919. https://doi.org/10.1111/bjh.19372