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721.ALLOGENEIC TRANSPLANTATION: CONDITIONING REGIMENS, ENGRAFTMENT AND ACUTE TOXICITIES

Haploidentical Hematopoietic Stem Cell Transplantation with Post-Transplant Cyclophosphamide in the Chilean National Health System. a Single Center Study

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Haploidentical peripheral blood stem cell transplantation with post-transplant cyclophosphamide (Haplo-PTCy) is the most common transplantation modality in low-and-middle-income countries (LMIC). Registry data has shown comparable outcomes when using haploidentical donors versus Matched Unrelated Donors (MUD) in patients with acute leukemias. In the Chilean Public Health System Haplo-PTCy was incorporated in 2016 for adults up to 60 years old.

We analyzed all adult patients who received an Haplo-PTCy at Hospital del Salvador, in a prospective registry study between 2016 and 2021. The primary outcome was overall survival (OS). Secondary outcomes were event-free survival (EFS), cumulative incidence of relapse, and incidence of grade II-IV acute graft-versus-host disease (aGVHD) at day +100. Overall survival and EFS were estimated using the Kaplan-Meier method. The cumulative incidence of relapse was calculated using relapse as the primary event and death without relapse as a competing event. Acute GVHD is shown as absolute incidence at day +100. All statistical analyses were performed with R. This study was done in compliance with the Helsinki Declaration and was approved by the Institutional Review Board.

Eighty-five Haplo-PTCy were performed in 82 patients (Table 1). Three-second Haplo-PTCy were excluded from this analysis. The median age was 25 years (range, 15-51), and 65% were male. Ninety-four percent of patients had a neoplastic disease (77/82), and the most common diagnosis was acute lymphoblastic leukemia (57%). Forty-seven percent proceeded to transplant in the first complete response. Most of the patients (76%) presented a low hematopoietic cell transplantation (HCT)-specific comorbidity index. Conditioning was mostly myeloablative (96%). The median dose of CD34+ cells infused was $8.1 \times 10^6/\text{kg}$ (range, 2.4-10.0). No patient needed a desensitization regimen. Cytokine release syndrome (CRS) was common (86%) but no grade 3 CRS was observed. Primary graft failure was observed in one patient (1.2%). Poor graft function was observed in 11 patients (13%). Five patients (6.1%) died before engraftment. The incidence of grade II-IV aGVHD at day +100 was 29% (grade IV was not observed). With a median follow-up of 33 months (range 0-84), the estimated 3-year OS and EFS were 68.3% (95% CI 59-79%) and 64.6% (95% CI 55-76%), respectively (Figure 1). In patients with neoplastic disease (n=77), the 3-year cumulative incidence of relapse was 23% (95% CI 15-33%).

Haplo-PTCy is feasible in LMIC. This cohort of cases, mostly young patients with neoplastic disease, shows encouraging survival with an acceptable aGVHD and relapse incidence.

Disclosures Undurraga: AbbVie: Membership on an entity's Board of Directors or advisory committees; Janssen: Membership on an entity's Board of Directors or advisory committees; Novartis: Membership on an entity's Board of Directors or advisory committees; Pfizer: Membership on an entity's Board of Directors or advisory committees; Roche: Membership on an entity's Board of Directors or advisory committees; Janssen: Speakers Bureau; Novartis: Speakers Bureau; Pfizer: Speakers Bureau.

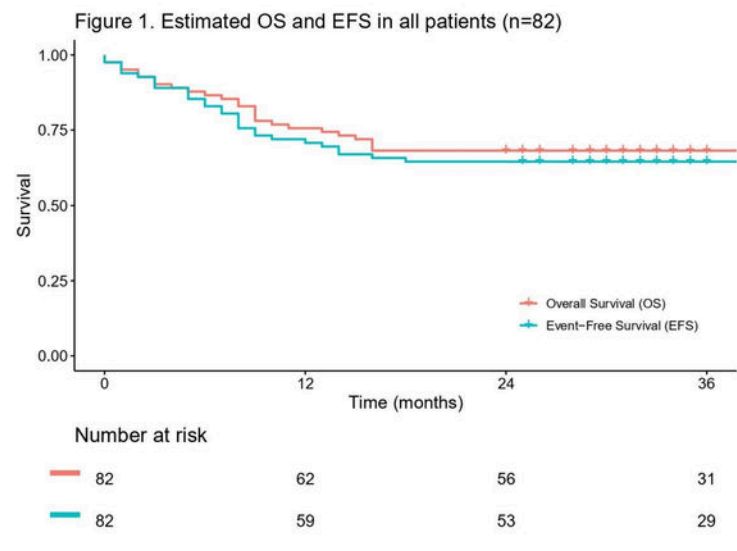


Figure 1

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Table 1. Patient Characteristics and Transplant Complications	
Disease, n (%)	
ALL	47 (57%)
AML/MDS	25 (31%)
SAA	3 (4%)
Other	7 (8%)
Type of MAC conditioning, n (%)	
FluTBI	34 (41%)
BuFlu	26 (32%)
CyTBI	10 (12%)
Other	12 (15%)
Donor relationship, n (%)	
Sibling	49 (60%)
Parent	17 (21%)
Other	16 (19%)
Donor-Specific Antibodies, n (%)	
Negative	71 (87%)
Positive, < 1000 MFI	1 (1%)
Not assessed	10 (12%)
ABO Incompatibility, n (%)	
No/Minor	69 (84%)
Major/bidirectional	13 (16%)
Donor/Receptor CMV status, n (%)	
D+/R+	70 (85%)
D+/R-	8 (10%)
Other	4 (5%)
CMV reactivation at day +100, n (%)	
PTLD at day +100, n (%)	3 (4%)
cGVHD onset day, median (range)	
Mild / Moderate	+187 (+112 to +562)
Extensive	5 (6%)
Death during follow-up, n (%)	
Relapse	17 (21%)
Transplant Related Mortality	8 (10%)
Other (COVID-19 Pneumonia)	1 (1%)
ALL: Acute Lymphoblastic Leukemia, AML/MDS: Acute Myeloid Leukemia and Myelodysplastic Syndrome, SAA: Severe Aplastic Anemia, MAC: Myeloablative conditioning, CMV: cytomegalovirus, cGVHD: Chronic Graft versus Host disease.	