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IRANIAN SOCIETY OF MEDICAL ONCOLOGY AND HEMATOLOGY
ISMOH

Haploidentical Transplantation Challenges

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REGULAR ARTICLE

blood advances

Effect of donor characteristics on haploidentical transplantation with posttransplantation cyclophosphamide

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- We studied the association between donor characteristics and transplant outcomes after T-cell-replete HLA-haploidentical transplantation using PT-Cy in 928 adults with hematologic malignancy
- Sixty-five centers contributed patients,
- Eligible patients were aged 18 years and older with acute myeloid leukemia (AML), ALL,MDS, Lymphoma,..
- Excluded were regimens that included in vivo T-cell depletion (n = 29). The Institutional Review Board of the National Marrow Donor Program approved this study.

- The primary endpoint was overall survival. Death from any cause was considered an event.
- Primary and secondary graft failure were considered as a single outcome.
- Relapse/progression was defined as disease recurrence(morphologic,cytogenetic, or molecular) or progression.
- Nonrelapse mortality was defined as death in remission.
- Grade II-IV acute GVHD and chronic GVHD were based on reports from each transplant center, using standard criteria.

Table 1. Donor, patient, disease and transplant characteristics

Characteristics	Number (%)
Donor age, y	
10-29	279 (30)
30-49	420 (45)
50-80	229 (25)
Donor-recipient relationship	
Parent	120 (13)
Sibling	358 (39)
Offspring	450 (48)
Donor-recipient sex match	
Male donor/male recipient	335 (36)
Male donor/female recipient	208 (23)
Female donor/male recipient	224 (24)
Female donor/female recipient	161 (17)
Donor-recipient ABO match	
Matched	530 (57)
Major mismatch	147 (16)
Minor mismatch	114 (12)
Not reported	137 (15)
Donor-recipient cytomegalovirus serostatus match	
Donor negative/recipient negative	232 (25)
Donor negative/recipient positive	234 (25)
Donor positive/recipient negative	119 (13)
Donor positive/recipient positive	335 (36)

cteristics	
Number (%)	
279 (30)	
420 (45)	
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224 (24)	
161 (17)	
530 (57)	
147 (16)	
114 (12)	
137 (15)	
232 (25)	

Table 1. (continued)

Characteristics
Myelodysplastic syndrome
Non-Hodgkin lymphoma
Hodgkin lymphoma
Disease risk index
Low risk
Intermediate risk
High risk
Graft type*
Bone marrow
Peripheral blood
Conditioning regimen
Myeloablative
Total body irradiation + fludarabine
Total body irradiation + other agents
Busulfan + cyclophosphamide
Busulfan + fludarabine
Reduced intensity
Total body irradiation + cyclophosphamide + fludarabine
Total body irradiation + other agents
Melphalan + fludarabine

Table 2. Effect of patient age, donor-recipient relationship, and donor age on overall mortality, nonrelapse mortality, and relapse

	Overall mortality, hazard ratio (95% CI)*	Nonrelapse mortality, hazard ratio (95% CI)†	Relapse, hazard ratio (95% CI)‡
Patient age, y/donor-recipient relationship			
Age 18-54/parent donor	1.00, $P < .0001$§	1.00, $P = .003$§	1.00, $P = .18$§
Age 18-54/sibling donor	0.87 (0.61-1.24), $P = .44$	0.96 (0.51-1.82), $P = .90$	0.75 (0.52-1.09), $P = .14$
Age 18-54/offspring donor	0.92 (0.61-1.38), $P = .67$	1.47 (0.75-2.88), $P = .26$	0.65 (0.41-1.03), $P = .07$
Age 55-78/sibling donor	1.53 (1.04-2.23), $P = .030$	2.36 (1.26-4.45), $P = .007$	0.84 (0.54-1.30), $P = .43$
Age 55-78/offspring donor	1.57 (1.13-2.20), $P = .008$	1.84 (1.04-3.25), $P = .04$	0.96 (0.66-1.39), $P = .82$
Patient age/donor age, y			
Age 18-54/donor age 10-29	1.00, $P < .0001$§	1.00, $P = .001$§	1.00, $P = .28$§
Age 18-54/donor age 30-80	1.07 (0.79-1.44), $P = .64$	1.12 (0.67-1.86), $P = .42$	1.13 (0.82-1.57), $P = .44$
Age 55-78/donor age 10-29	1.57 (1.09-2.26), $P = .015$	1.34 (0.76-2.56), $P = .37$	1.49 (0.99–2.24), $P = .06$
Age 55-78/donor age 30-80	1.82 (1.38-2.39), $P < .0001$	2.09 (1.32-3.34), $P = .002$	1.24 (0.89-1.71), $P = .19$

*Adjusted for recipient CMV seropositivity, disease risk index, and disease.
†Adjusted for recipient CMV seropositivity and graft type.
‡Adjusted for disease risk index, disease and graft type.
§This *P* value represents the level of significance for the overall Cox regression model. *P* values for paired comparisons within the model were considered significant only when the *P* valu
for the overall model was significant.

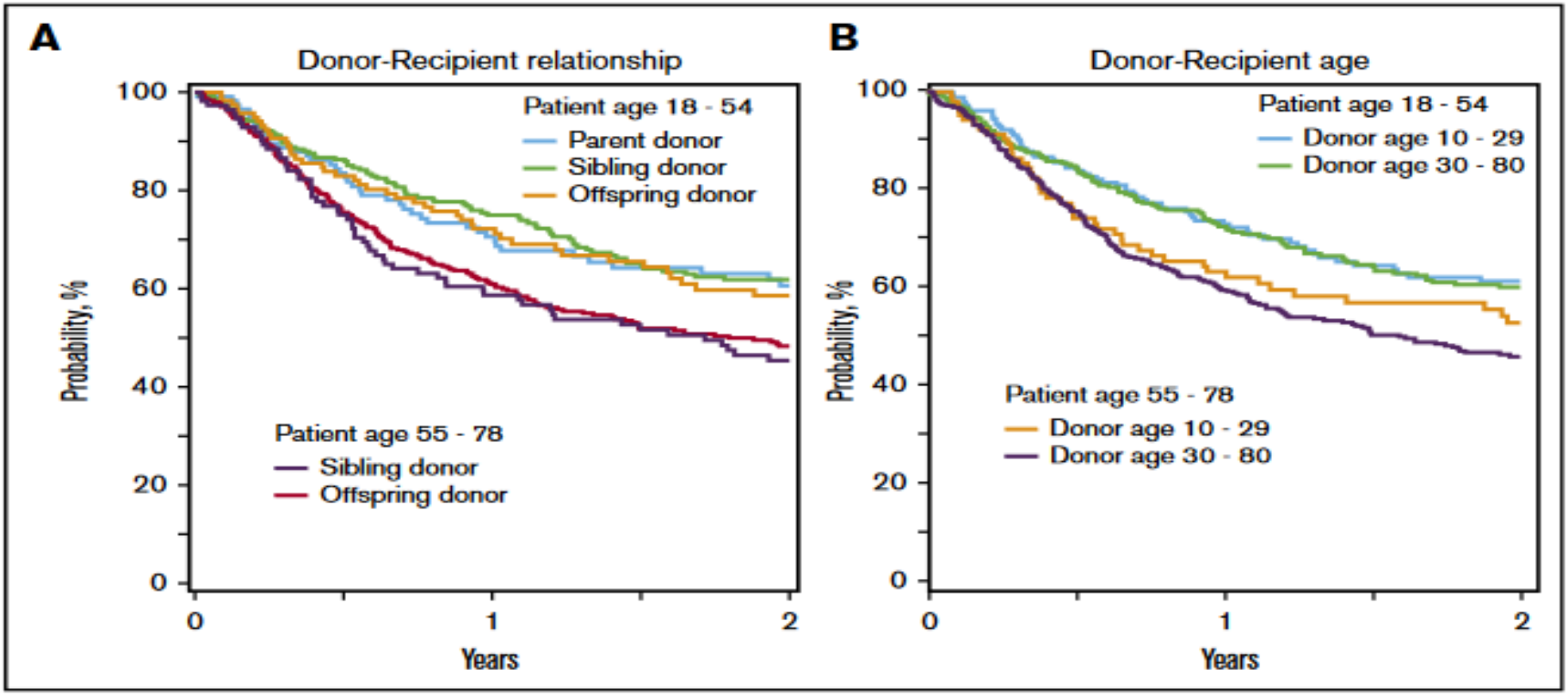
Relapse

- None of the donor characteristics studied except transplantation peripheral blood was associated with relapse or Nonrelapse.

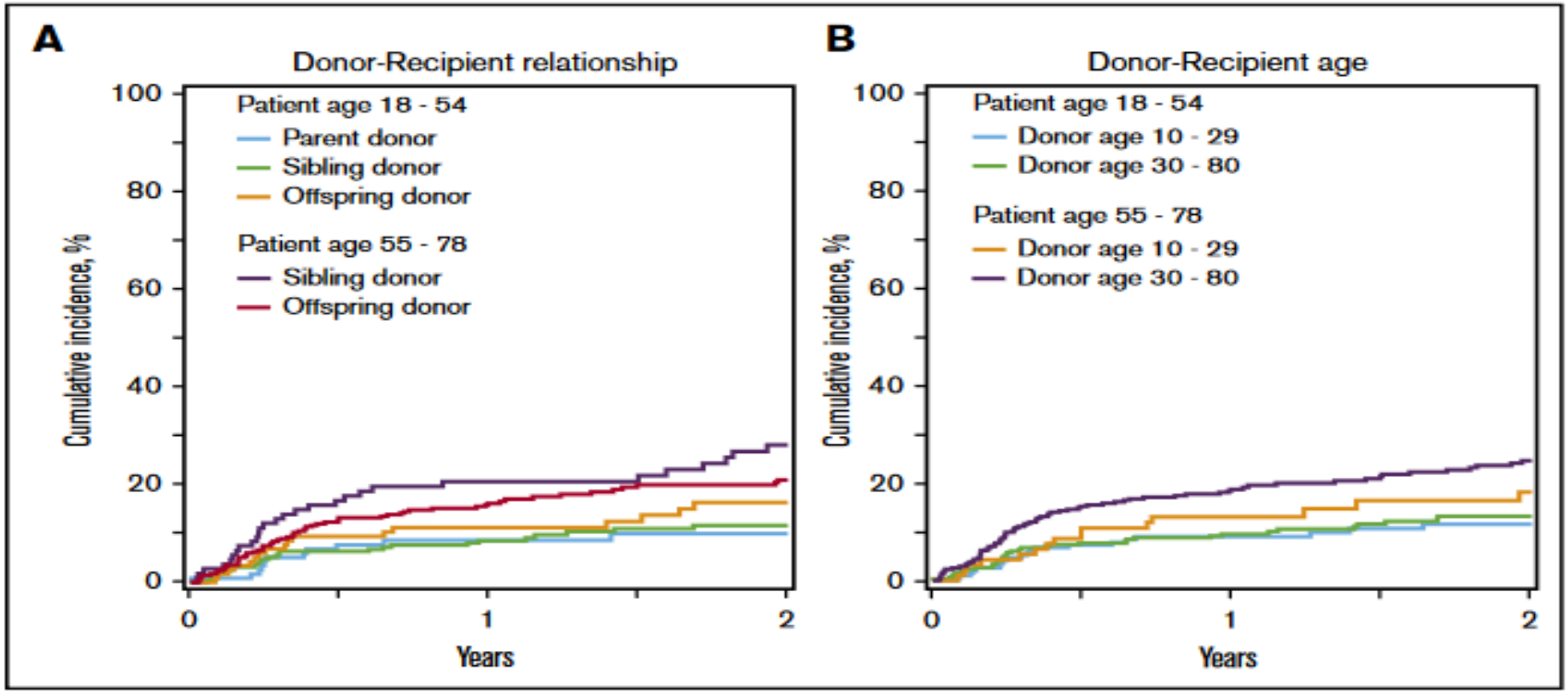
- Compared with AML, Relapse risks were lower for myelodyspla syndrome (HR, 0.64; 95% CI, 0.45-0.91; P 5 .01) and Hodgkin lymphoma (HR, 0.49; 95% CI, 0.28-0.87; P 5 .015), but not nor Hodgkin lymphoma (HR, 0.83; 95% CI, 0.58-1.19; P 5 .30) or A

- Compared with low disease risk index, risks were higher with intermediate (HR, 2.44; 95% CI, 1.34-4.45; P 5 .004) and high

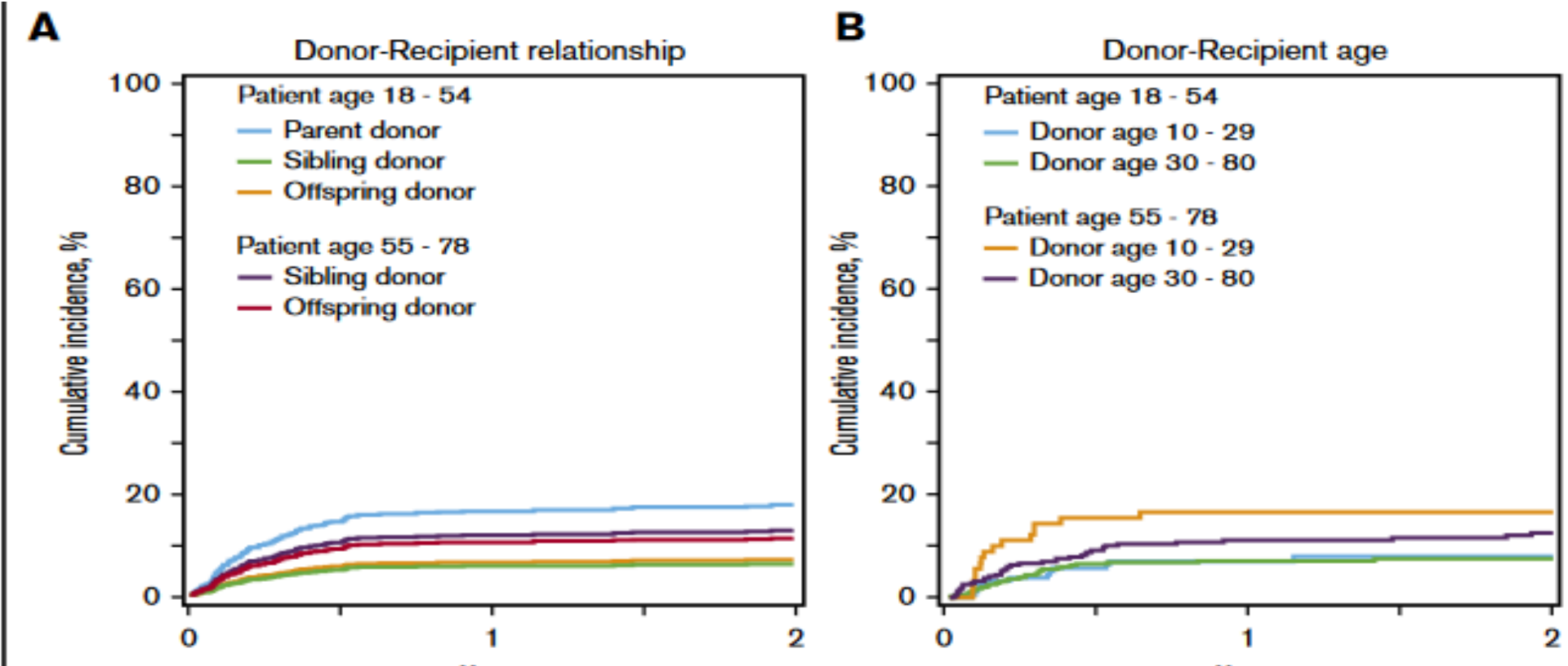
Overall Survival



Non Relapse Mortality



Graft Failure



Discussion

- patient and disease characteristics are more important than either the age of the donor or donor-recipient relationship with regard to survival and GVHD.
- In adults, transplantation of grafts from a parent was associated with higher graft failure rate.
- The higher risks for acute and chronic GVHD and the absence of a survival advantage with peripheral blood suggest that with the PT-Cy approach for haplo transplantation.

- There is broad agreement that presence of donor-specific antibodies in the recipient is associated with graft failure.
  - best studied at individual centers to establish center-specific thresholds for desensitization.
- Other donor characteristics such as sex, parity, age and blood group ABO match were not associated with transplant outcomes
- However, an EBMT report that acute GVHD risks were higher with bidirectional ABO mismatching only.

ELSEVIER

Biology of Blood and Marrow Transplantation

journal homepage: www.bbmt.org

ASBMT
American Society for Blood and Marrow Transplantation

Selecting the Best Donor for Haploidentical Transplant: Impact of HLA, Killer Cell Immunoglobulin-Like Receptor Genotyping, and Other Clinical Variables

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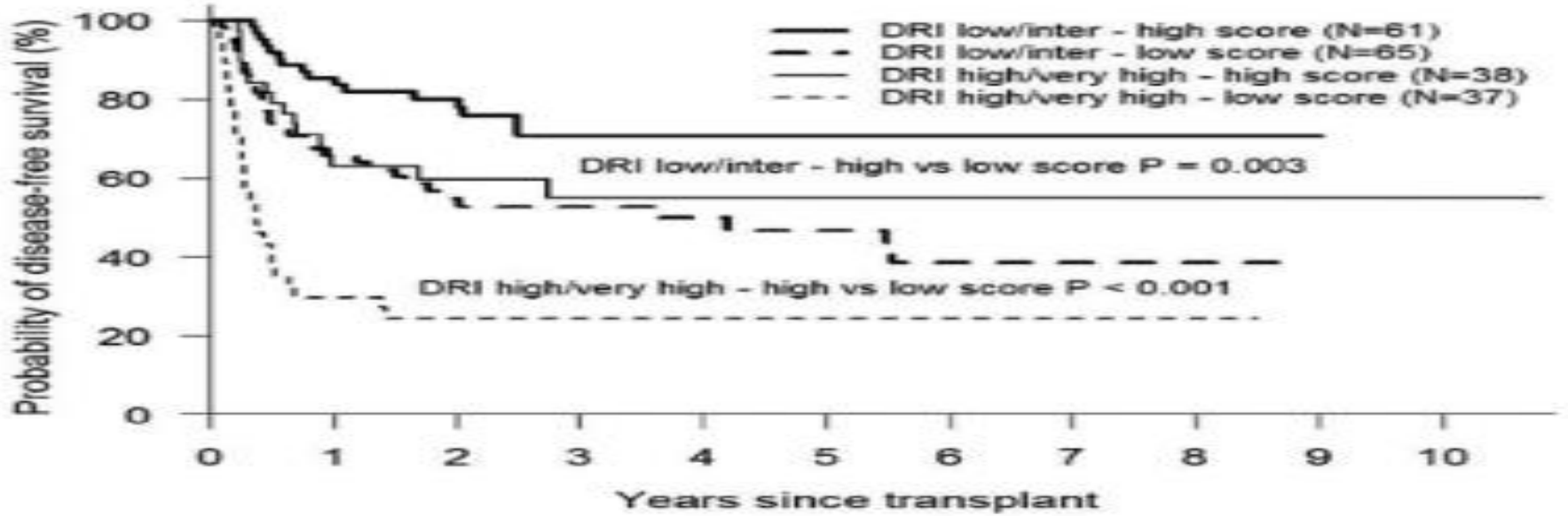
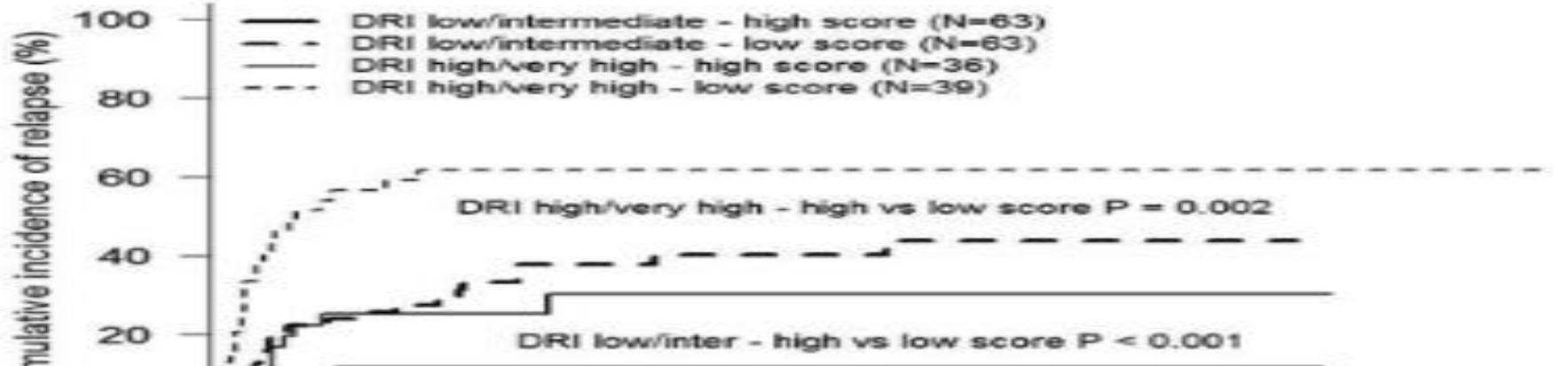
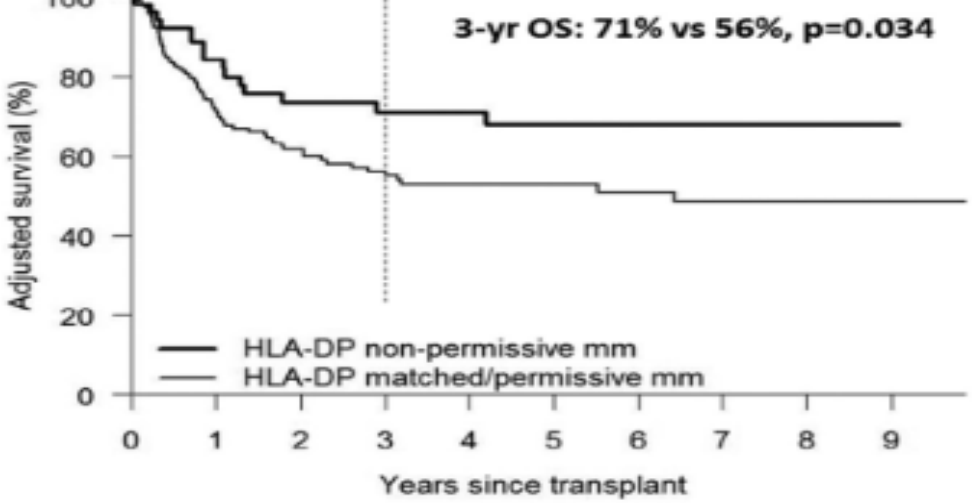
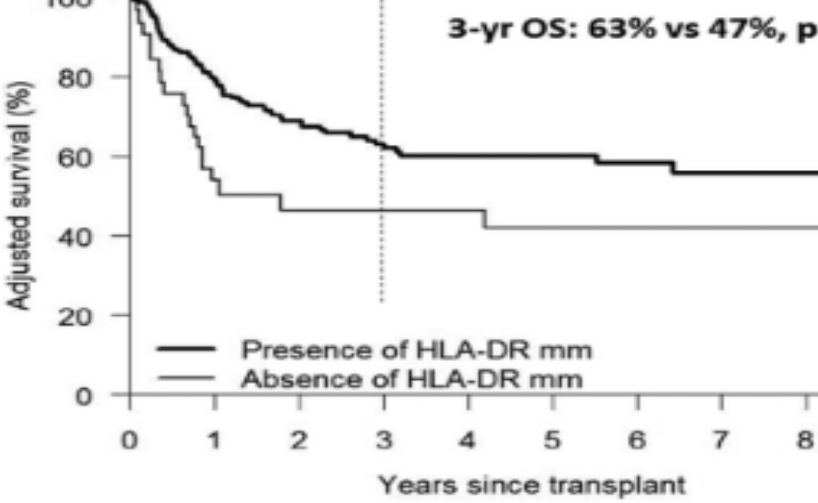
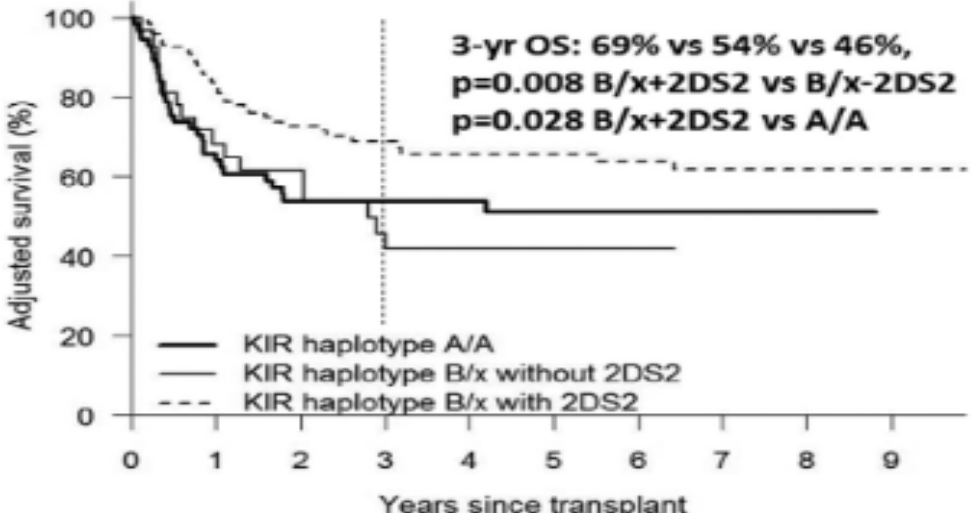

Probability of disease-free survival (%)
100
80
60
40
20
0
0
1
2
3
4
5
6
7
8
9
10
Years since transplant
DRI low/inter - high score (N=61)
DRI low/inter - low score (N=65)
DRI high/very high - high score (N=38)
DRI high/very high - low score (N=37)
DRI low/inter - high vs low score P = 0.003
DRI high/very high - high vs low score P < 0.001

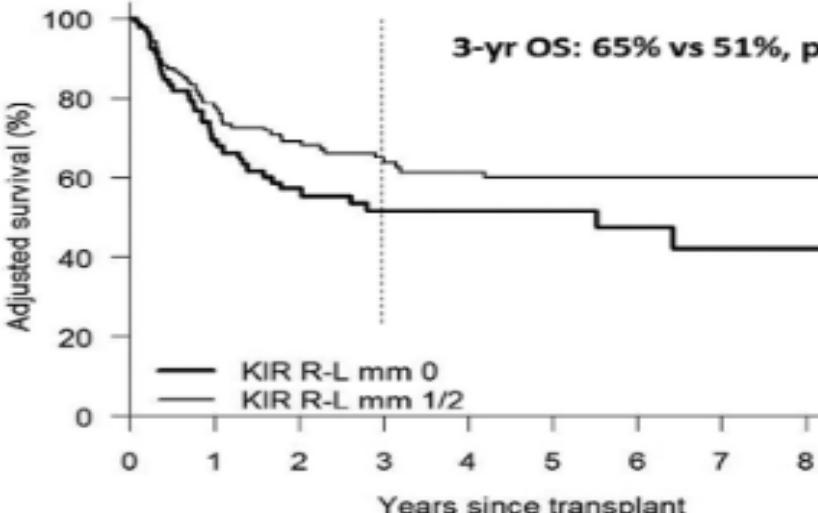
B

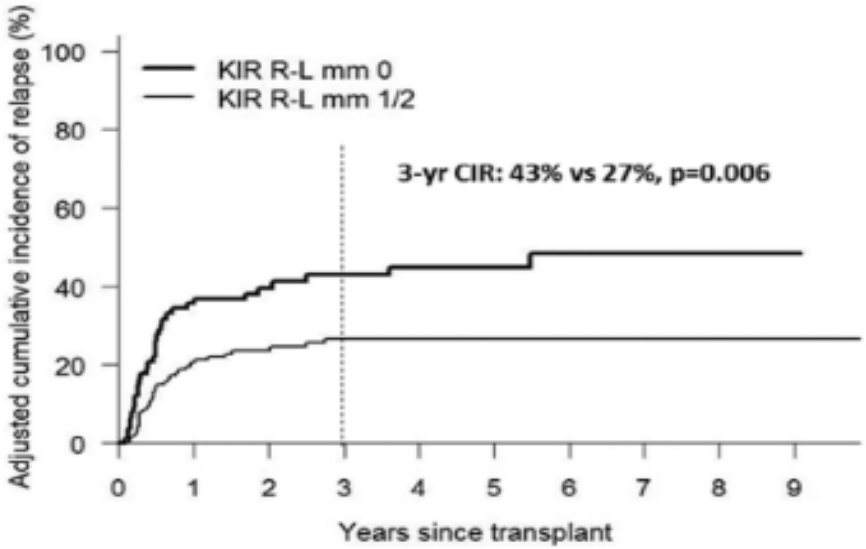

100
80
60
40
20
DRI low/intermediate - high score (N=63)
DRI low/intermediate - low score (N=63)
DRI high/very high - high score (N=36)
DRI high/very high - low score (N=39)
DRI high/very high - high vs low score P = 0.002
DRI low/inter - high vs low score P < 0.001

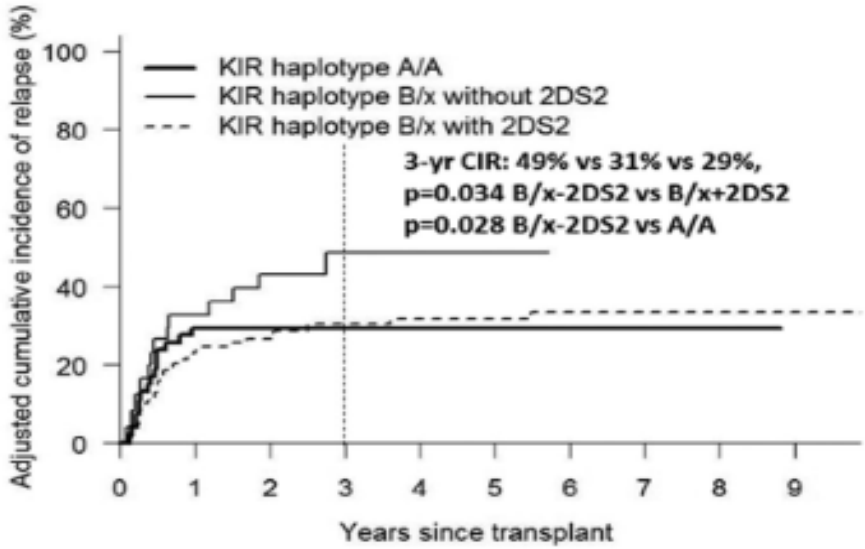

3-yr OS: 71% vs 56%, p=0.034
Adjusted survival (%)
HLA-DP non-permissive mm
HLA-DP matched/permissive mm
Years since transplant

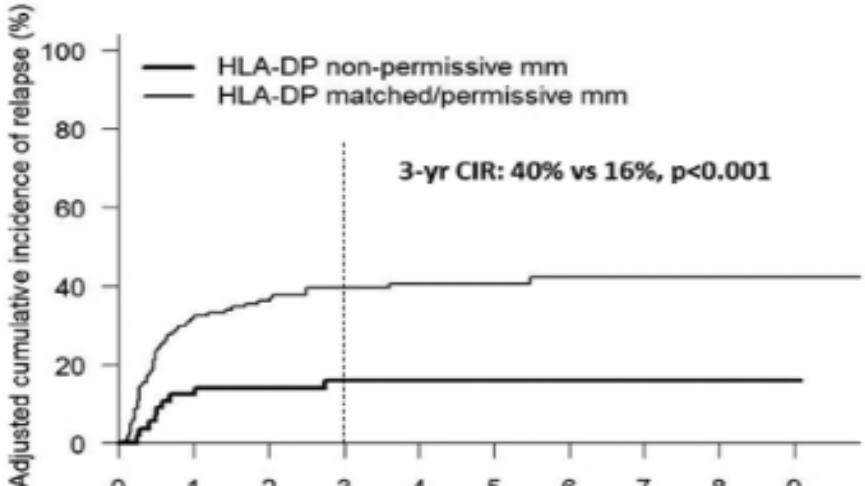

3-yr OS: 63% vs 47%, p
Adjusted survival (%)
Presence of HLA-DR mm
Absence of HLA-DR mm
Years since transplant

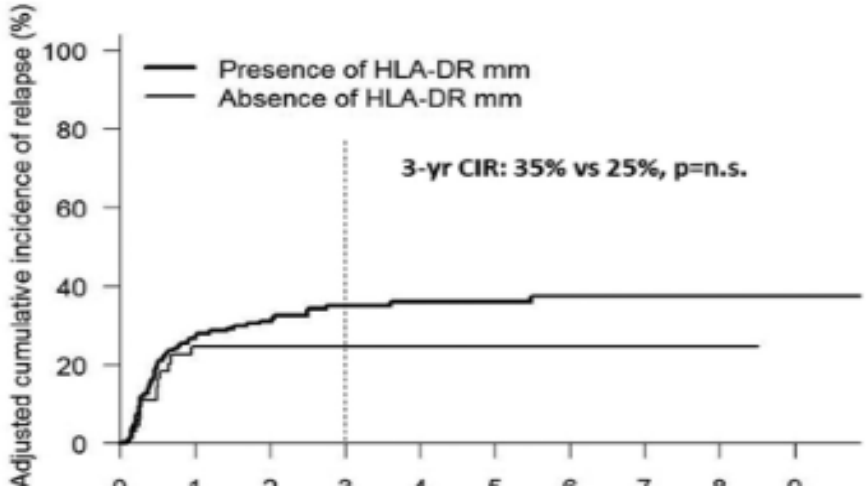

3-yr OS: 69% vs 54% vs 46%,
p=0.008 B/x+2DS2 vs B/x-2DS2
p=0.028 B/x+2DS2 vs A/A
Adjusted survival (%)
KIR haplotype A/A
KIR haplotype B/x without 2DS2
KIR haplotype B/x with 2DS2
Years since transplant

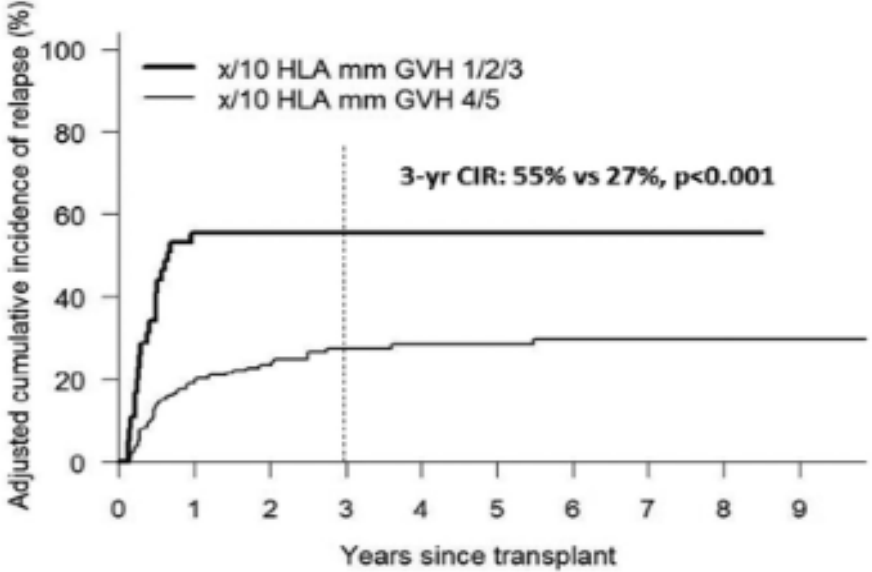

3-yr OS: 65% vs 51%, p
Adjusted survival (%)
KIR R-L mm 0
KIR R-L mm 1/2
Years since transplant

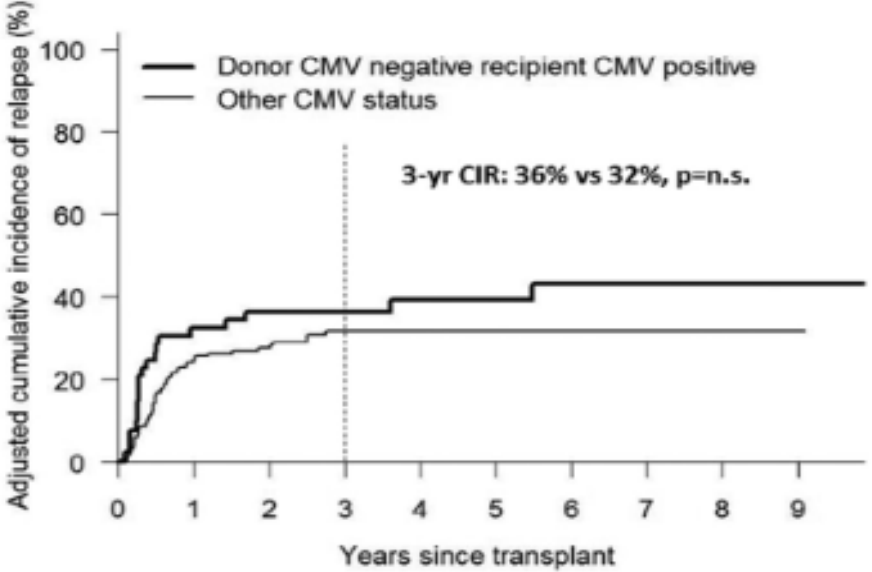

KIR R-L mm 0
KIR R-L mm 1/2
3-yr CIR: 43% vs 27%, p=0.006
Adjusted cumulative incidence of relapse (%)
Years since transplant

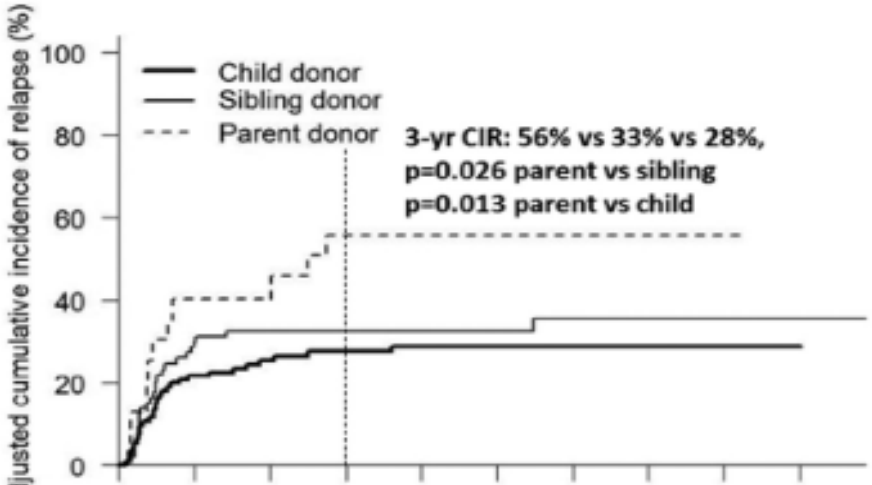

KIR haplotype A/A
KIR haplotype B/x without 2DS2
KIR haplotype B/x with 2DS2
3-yr CIR: 49% vs 31% vs 29%,
p=0.034 B/x-2DS2 vs B/x+2DS2
p=0.028 B/x-2DS2 vs A/A
Adjusted cumulative incidence of relapse (%)
Years since transplant


HLA-DP non-permissive mm
HLA-DP matched/permissive mm
3-yr CIR: 40% vs 16%, p<0.001
Adjusted cumulative incidence of relapse (%)


Presence of HLA-DR mm
Absence of HLA-DR mm
3-yr CIR: 35% vs 25%, p=n.s.
Adjusted cumulative incidence of relapse (%)


x/10 HLA mm GVH 1/2/3
x/10 HLA mm GVH 4/5
3-yr CIR: 55% vs 27%, p<0.001
Adjusted cumulative incidence of relapse (%)
Years since transplant


Donor CMV negative recipient CMV positive
Other CMV status
3-yr CIR: 36% vs 32%, p=n.s.
Adjusted cumulative incidence of relapse (%)
Years since transplant


Child donor
Sibling donor
Parent donor
3-yr CIR: 56% vs 33% vs 28%,
p=0.026 parent vs sibling
p=0.013 parent vs child
Adjusted cumulative incidence of relapse (%)

HLA and KIR Genotypes

- Other than HLA and KIR genotypic variation, other donor characteristics associated with improved survival in the current study were donor CMV seropositivity and donor–recipient relationship (child > sibling > parent).

- CMV-seropositive transplant recipients continue to show a significantly higher risk of mortality, Our study indeed showed inferior survival of CMV-seropositive recipients transplanted with seronegative donors.

  - CMV-seropositive donors are generally preferred for CMV-seropositive recipients because of a lower risk of CMV reactivation, CMV disease, and NRM

- In the setting of ATG-based T cell–replete haplo HSCT (Beijing protocol), only maternal, but not paternal, donors were associated with higher NRM and inferior survival

DISCUSSION

- To date, there are no published reports of HLA disparity affecting transplant outcomes in T cell–replete haplo HSCT
- In our study specific class II HLA mismatches in HLA-DRB1 and HLA-DPB1 (nonpermissive mismatch) were associated with superior OS.
- The presence of HLA-DR allelic mismatch has shown a similar protective effect of HLA-DR disparity on survival, that effect was mostly due to relapse protection.
- There was no association of HLA disparity with acute GVHD

Donor KIR genotype

- Donor KIR R-L mismatch was significantly associated with improvements in OS (HR, .63; P = .050) and DFS (HR, .57;P = .012).

- In addition, KIR B/x with 2DS2 (KIR B/x haplotype with presence of KIR2DS2) was associated with superior OS (HR, .43; P = .005) and DFS (HR, .45; P = .003) when compared with donors with KIR A/A haplotype.

- Furthermore, OS and DFS were also improved when compared with KIR B/x haplotype donors without KIR2DS2.

- The biological explanation is unknown but NK-mediated alloreactivity has been previously proposed to induce enhanced efficacy and GVHD protection in the context of T cell-depleted Haplo-SCT

Bone Marrow Transplantation
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ARTICLE

Second haploidentical stem cell transplantation for primary graft failure

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- The aim of the present study was to assess the incidence of PrGF in a series of 503 unmanipulated bone marrow HAPLO transplants, and to report the outcome of a second HAPLO transplant in 19 patients in whom PrGF occurred.

- The overall risk of PrGf is relatively low, possibly because the vast majority of patients are prepared with a myeloblative conditioning regimen.

- PrGF was defined as the lack of neutrophil recovery by day +28, with donor chimerism <10%.

- Indeed we recorded only PrGF (1.4%) and a stepwise increased risk with TBF3 (2.9%), TBF2 (5.3%), TBF1 or 1 day of busulfan (12.5%) on patients.

- All 19 patients had autologous chimerism on the first bone marrow aspirate (days +20, +30), with <10% donor chimerism; one patient had 15% on first examination and 0% on second evaluation.

Table 1 Clinical charactersitics of 19 patients at first HAPLO BMT.

N	RG	RA	Dx	Phase	DSA	DG	DA	Rel.	SC	Cell dose	CD34
1	M	60	MDS	ADV	POS	M	27	SON	BM	2.2	2.4
2	F	56	MDS	ADV	POS	M	33	SON	BM	4.8	9.6
3	F	64	MDS	ADV	NEG	M	33	SON	BM	3.1	3.7
4	F	65	AML	CR1	POS	M	35	SON	BM	3.1	4.1
5	M	30	AML	CR1	NEG	F	50	MOTH	BM	2.0	0.7
6	F	54	MF	ADV	POS	M	25	SON	BM	4.3	5.3
7	M	65	MF	ADV	NA	M	37	SON	BM	2.9	3.5
8	F	67	MF	ADV	NA	F	31	DAUG	BM	2.4	1.8
9	M	63	AML	ADV	NEG	F	59	SIB	BM	2.4	1.3
10	F	20	AML	CR1	NEG	F	39	MOTH	BM	5.6	5.1
11	F	40	AML	CR2	POS	F	20	DAUG	BM	4.0	5.6
12	F	50	AML	CR1	POS	M	20	SON	BM	5.1	6.5
13	F	37	AML	CR1	NA	F	57	MOTH	BM	1.8	1.2
14	F	35	AML	CR1	NA	F	62	MOTH	BM	1.4	1.3
15	M	60	AML	CR1	NEG	F	33	DAUG	BM	3.6	4.4
16	F	45	AML	CR1	POS	F	46	SISTE	BM	3.8	1.0
17	M	58	MF	ADV	NEG	M	50	BROTH	BM	5.3	3.2
18	F	65	AML	CR1	POS	M	38	SON	BM	5.6	3.7
19	M	69	AML	FL	NEG	M	39	SON	BM	3.1	4.2

RG recipinets' gender, *DG* donors' gender, *MDS* myelodisplastic syndrome, *AML* acute myeloid leukemia, *MF* myelofibrosis, *CD* complete remission, *F* female, *M* male, *BM* bone marrow, *MOTH* mother, *DAUG*

Conditioning regimens

- (1) fludarabine 120 mg/m2 combined with TBI: 9–12 Gy (n = 74)
- (2) thiotepa 5 mg/kg on days −6 and −5 (total dose 10 mg/kg), busulfan 3.2 mg/kg, q24 h, on days −4, −3, −2 (total dose 9.6 mg/kg) and fludarabine 50 mg/m2 on days −4, −3, −2 (total dose 150 mg/m2), (n = 213).
- Busulfan was administered only on days −4, −3 (total dose 6.4 mg/kg), which we refer to as TBF2 (208 patients); or only on day −4, which we refer to as TBF1 (total dose 3.2 mg/kg) (n = 8).
- All patients received CsA starting day 0, at the dose of 3 mg/kg, until day +20 intravenously, then orally until day +180; MMF 15 mg/kg b.i.d. for 28 days and cyclophosphamide 50 mg/kg days +3 and +5

Second transplantation

- A second transplant was performed at a median interval of 42 days (range 34–82)
- The conditioning regimen for the second graft was the Baltimore protocol :CTX 14.5 mg/kg days −5, −6;fludarabine 30 mg/m2 days −6, −2; TBI 2 Gy day −1. Six patients received melphalan 30 mg/m2 instead of TBI 2 Gy.
- All donors were mobilized with G-CSF and unmanipulated PB cells were infused.
- GvHD prophylaxis was again PTCY 50 mg/kg days +3, +4, followed by CsA and MMF,The median CD34+ cell dose infused was 4.7 × 106/k
- DSA are possibly the strongest risk factor for graft failure after HAPLO transplants

Table 2 Clinical data of 19 patients at second HAPLO.

N	Donor 2nd Tx	Cond	Int-dd 1st–2nd	Engr 2nd Y/N	Int-dd 2nd–3rd	Donor 3rd Tx	Engr 3rd Y/N	aGvHD grade	Alive 1 year Y/N	Cause death <1 year	Time from 1st Tx
1	Same	TBI	42	Y	–	–	–	0	Y	–	
2	Other	TBI	41	Y	–	–	–	0	Y	–	
3	Other	TBI	82	Y	–	–	–	0	N	Infection	d 110
4	Same	TBI	37	Y	–	–	–	I	Y	–	
5	Other	TBI	49	Y	–	–	–	I	Y	–	
6	Other	TBI	41	Y	–	–	–	0	Y	–	
7	Same	TBI	41	No	–	–	–	N	108	Graft failure	
8	Same	TBI	44	Y	–	–	–	0	Y	–	
9	Same	TBI	66	Y	–	–	–	II	N	Relapse	d 168
10	Same	TBI	50	Y	–	–	–	0	Y	–	
11	Other	TBI	44	Y	–	–	–	II	Y	–	
12	Same	TBI	49	No	–	–	–	0	N	Infection	d 172
13	Same	MEL	36	No	–	–	–	0	N	Graft failure	d 3
14	Same	MEL	34	Y	–	–	–	0	Y	–	
15	Same	MEL	39	No	49	UD	Y	0	Y	–	
16	Same	MEL	38	Y	–	–	–	0	Y	–	
17	Same	TBI	42	Y	–	–	–	II	Y		
18	Same	MEL	41	Y	–	–	–	III	N	Gvhd	d 100
19	Other	MEL	53	No	48	UD	Y	II	Y	–	

Donor 2nd Tx donor of the 2nd transplant, *Same* same HAOPLO donor as in the 1st transplant, *Other* other HAPLO family member, *Int-d 1st–2nd* interval in days between the first and the second HAPLO transplant, *Engr 2nd* engraftment after a second HAPLO yes/no, *Int-dd 2nd–3r*

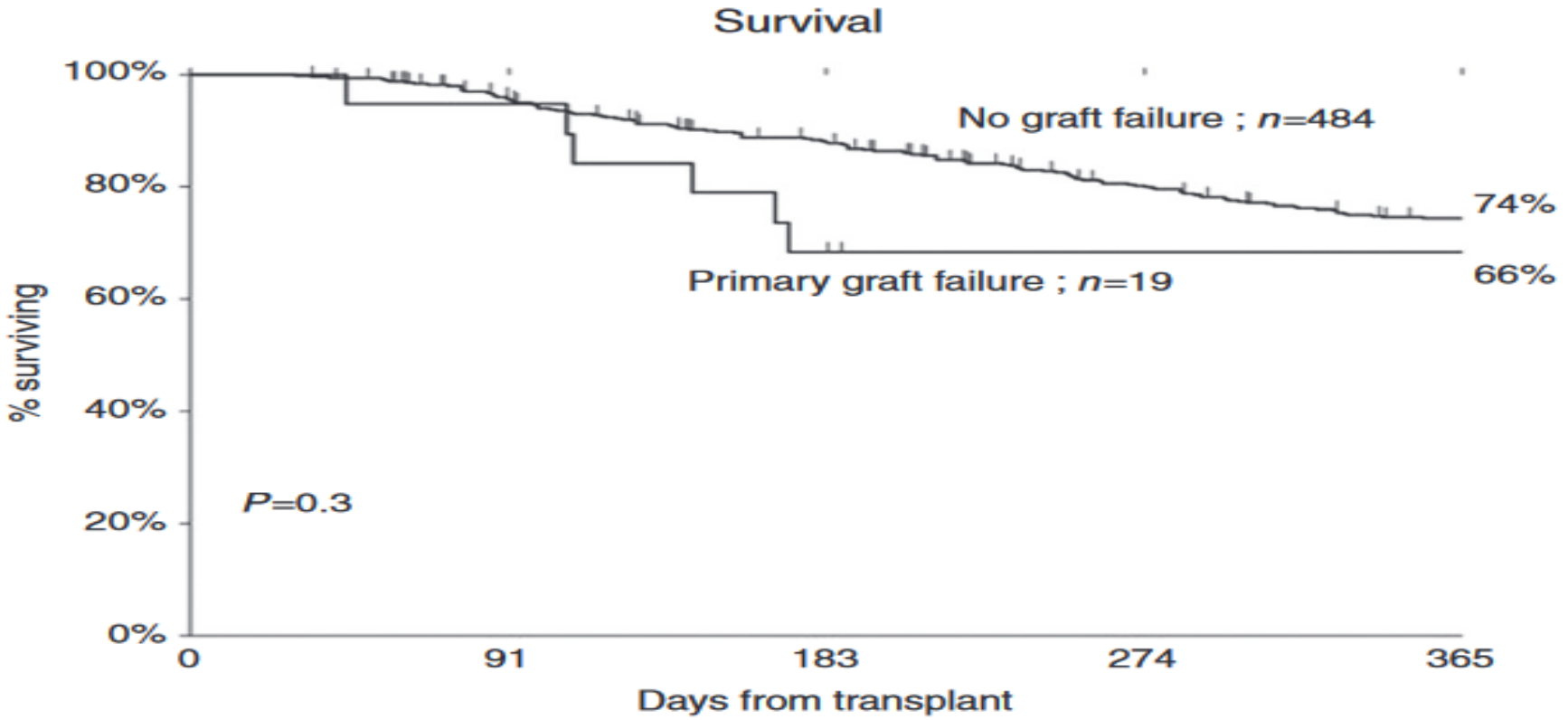

Fig. 1 1-years OS in patients with PrGF. Actuarial 1-year survival of patients who experienced primary graft failure (PrGF) ($n = 19$) or patients who engrafted and were alive on day +28 ($n = 484$).

conclusion

- Given that GvHD prophylaxis was exactly the same for all 503 patients, this would suggest a role of the intensity of the preparative regimen.

- There was no influence of patient's age on engraftment and ABO mismatch has been reported to influence the rate of engraftment

- patients experiencing primary failure to engraft after an unmanipulated marrow HAPLO graft can be rescued with an early second HAPLO transplant, using the same or another HAPLO donor , NOT a modified Baltimore regimen

- The overall risk of PrGf in our series is relatively low, possibly because the vast majority of patients are prepared with a myeloblative conditioning regimen,

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Post-transplant cyclophosphamide after matched sibling, unrelated and haploidentical donor transplants in patients with acute myeloid leukemia: a comparative study of the ALWP EBMT

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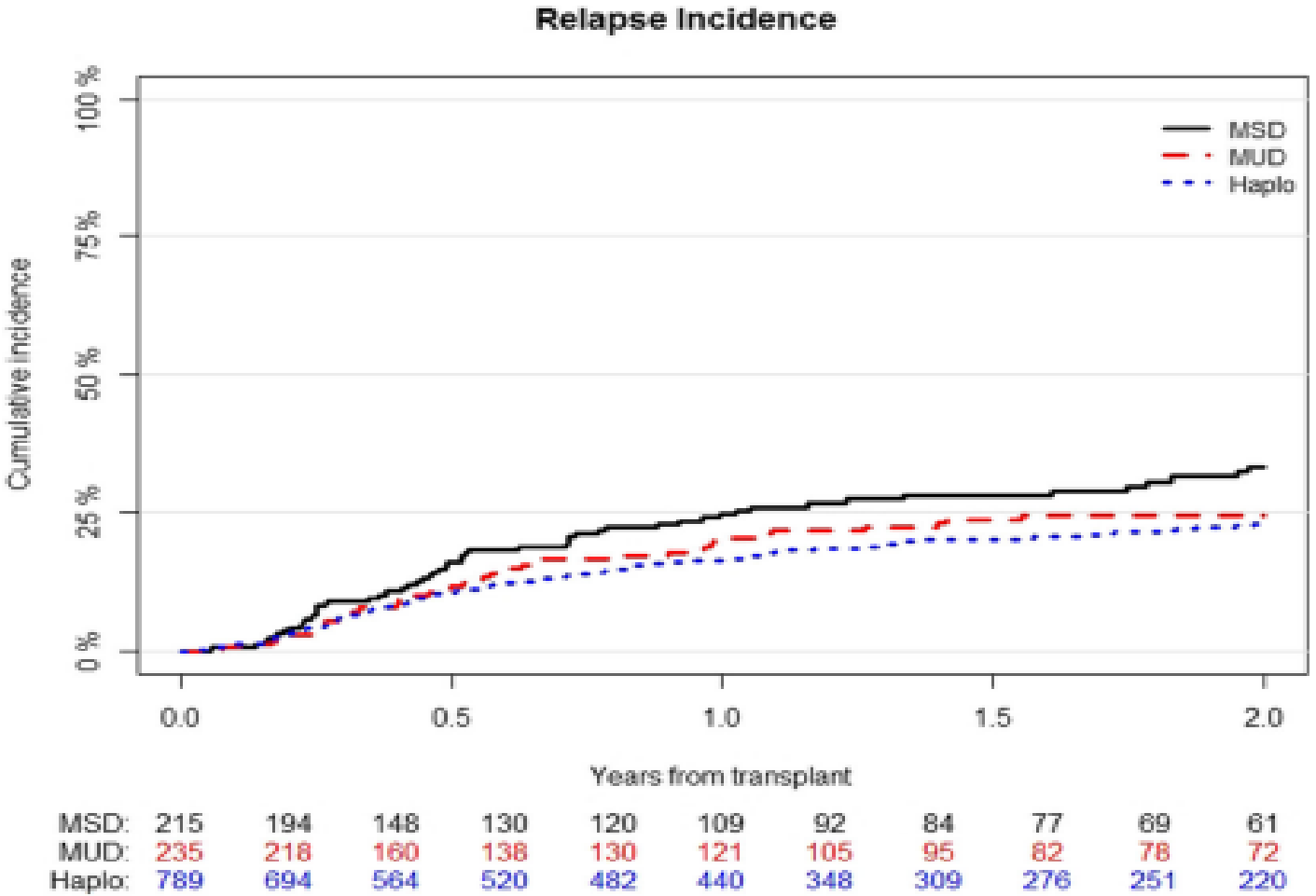
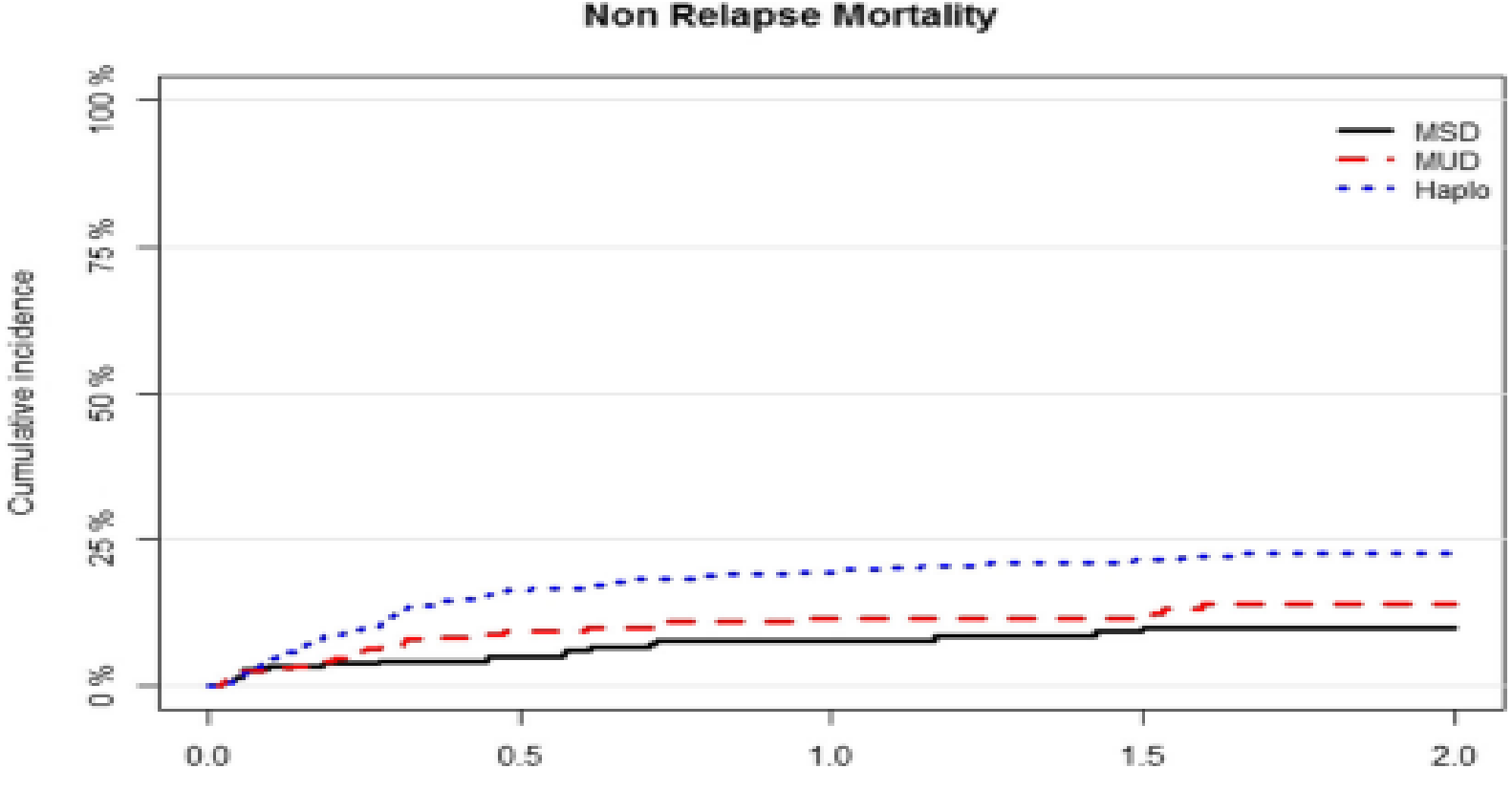
Male	693 (56)	117 (54)	132 (56)	444 (56)	
Female	546 (44)	98 (46)	103 (44)	345 (44)	
rnofsky performance status, *n* (%)					0.2
≥ 90	929 (79)	159 (77)	192 (83)	578 (78)	
< 90	251 (21)	48 (23)	39 (17)	164 (22)	
Missing	59	8	4	47	
ytogenetic risk category, *n* (%)					0.2
Standard	47 (6)	10 (8)	8 (6)	29 (5)	
Intermediate	543 (66)	92 (70)	87 (60)	364 (66)	
High	239 (29)	29 (22)	49 (34)	161 (29)	
Missing	410	84	91	235	
ype of AML, *n* (%)					< 0.001
De novo	1046 (84)	188 (87)	216 (92)	642 (81)	
Secondary	193 (16)	27 (13)	19 (8)	147 (19)	
onths from diagnosis to transplant, median (range)	5 (1-18)	4 (1-18)	5 (2-18)	5 (1-18)	< 0.001
onditioning intensity, *n* (%)					0.03
Myeloablative	725 (59)	122 (58)	116 (50)	487 (62)	
Reduced intensity	500 (41)	87 (42)	115 (50)	298 (38)	
Missing	14	6	4	4	
ype of conditioning, *n* (%)					0.2
Based on chemotherapy	950 (77)	159 (75)	172 (75)	619 (78)	
Based on TBI	287 (23)	54 (25)	63 (25)	170 (22)	
Missing	2	2	0	0	
em cell source, *n* (%)					< 0.001
Bone marrow	425 (34)	62 (29)	22 (9)	341 (43)	
Mobilized peripheral blood	814 (66)	152 (71)	213 (91)	448 (57)	
vivo T cell depletion, *n* (%)	164 (13)	29 (13)	63 (27)	72 (9)	< 0.001
vHD prophylaxis, *n* (%)					< 0.001
PTCy + 2 drugs	897 (72)	56 (26)	111 (47)	730 (93)	
PTCy + 1 drug	265 (21)	108 (50)	111 (47)	46 (6)	



g. 1 Cumulative incidence of relapse according to the type of transplant



Cumulative incidence of non-relapse mortality according to the type of transplant

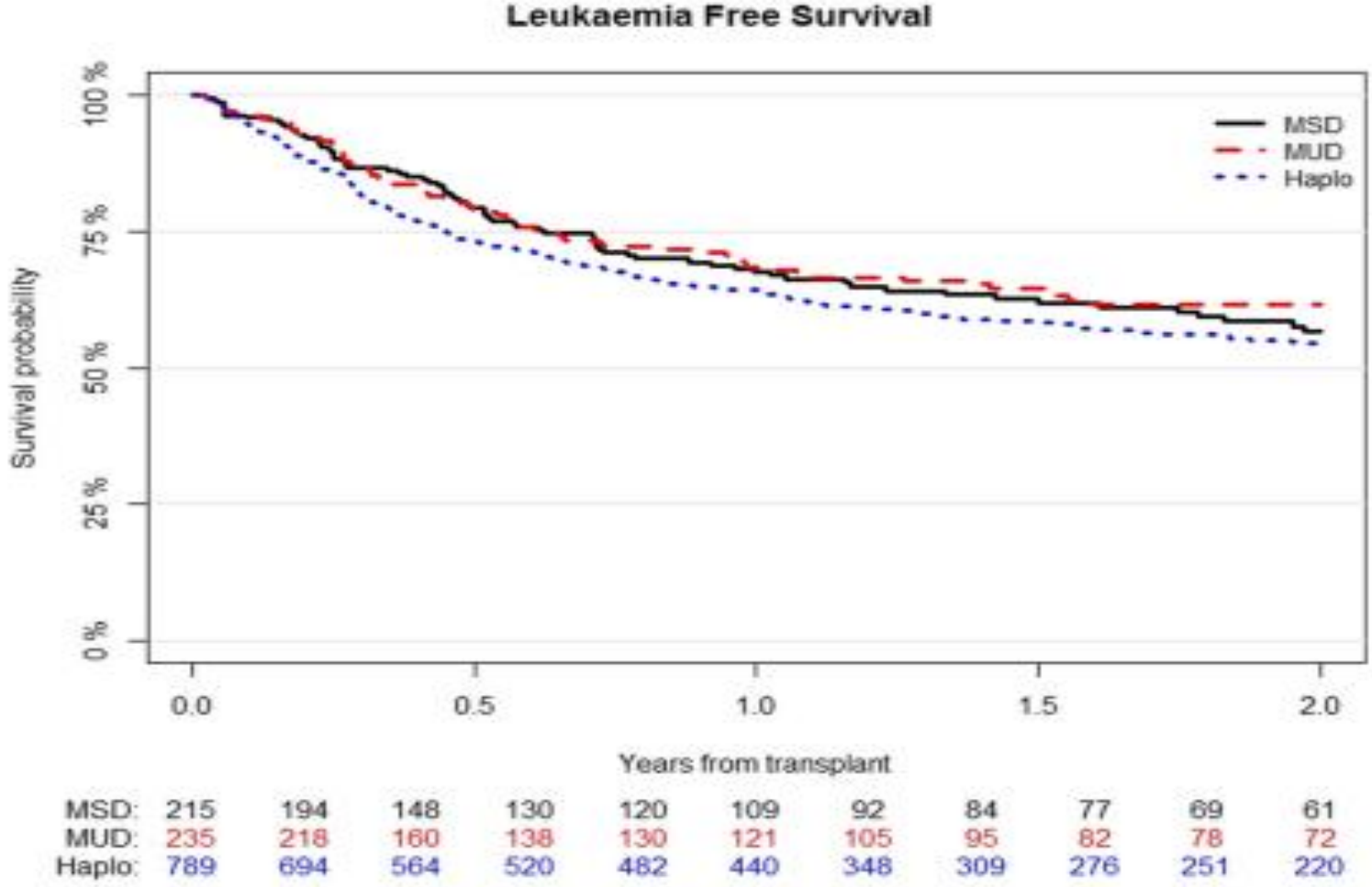


Fig. 3 Probability of leukemia-free survival according to the type of transplant

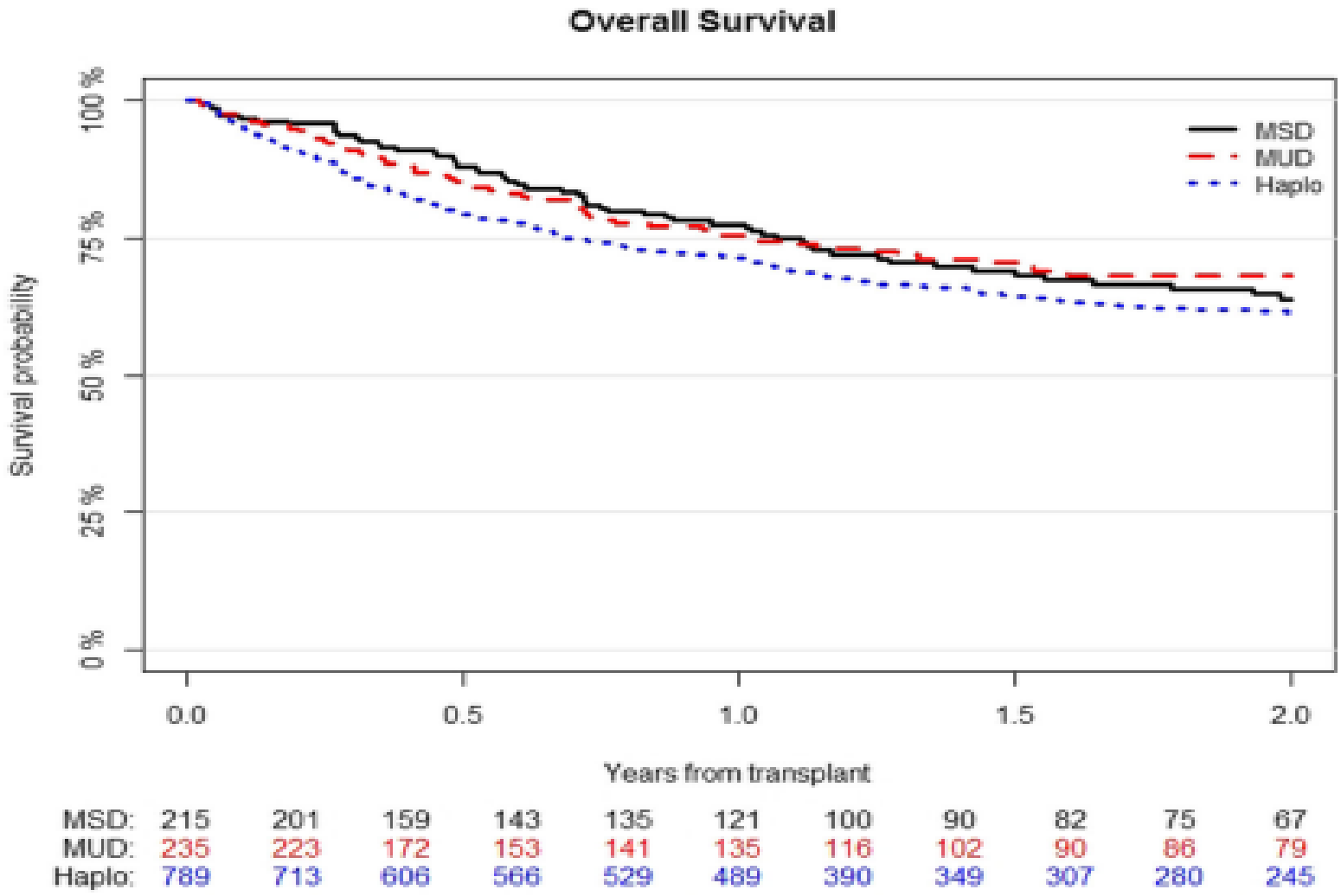


Fig. 4 Probability of overall survival according to the type of transplant

Conclusion

- Moreover, the group's previous study showed higher expression of CD on NK cells in haplo-HSCT-treated patients
- Haplo-SCT had higher rates of aGVHD and NRM, but lower relapse incidence.
- ALWP-EBMT has recently reported that the addition of IS drugs to PT enhances its effect and reduces the risk of severe chronic GvHD, reducin mortality and improving survival
- In multivariable analysis variables associated with better LFS were M good- or intermediate-risk cytogenetics and good performance status wh positive CMV serostatus of the recipient showed worse outcome.

- Under similar GvHD prophylaxis, a greater HLA disparity in the Haplo compared with the MSD and MUD settings could explain a higher NRM
  - Although the negative impact of Haplo in NRM was partially counterbalanced with a decreased incidence of relapse that translated in similar LFS

- EBMT also showed decreased relapse incidence in patients with high-risk cytogenetics undergoing Haplo.

- GRFS was 46% for Haplo, 42% for MUD, and 45% for MSD .

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