
Post-transplant Cyclophosphamide: a GvHD prophylaxis for any donor ?

Corso di Formazione GITMO-Transplant e terapie cellulari:
cellule, donatori e condizionamenti
8-9 ottobre, Ospedale di Udine/Italy

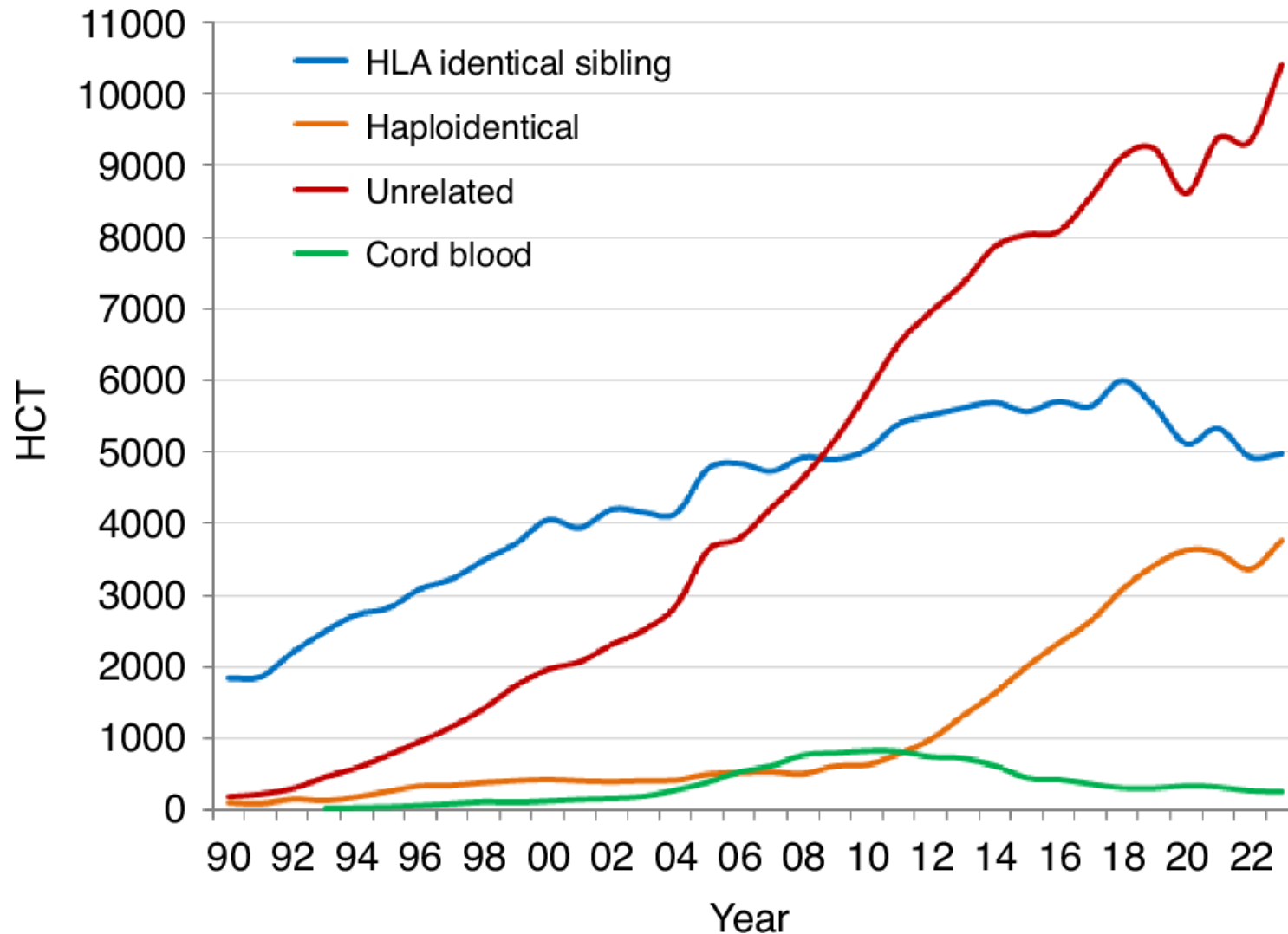
Nicolaus Kröger
Department of Hematology and Stem Cell Transplantation
University Medical Center Essen/Germany

Background

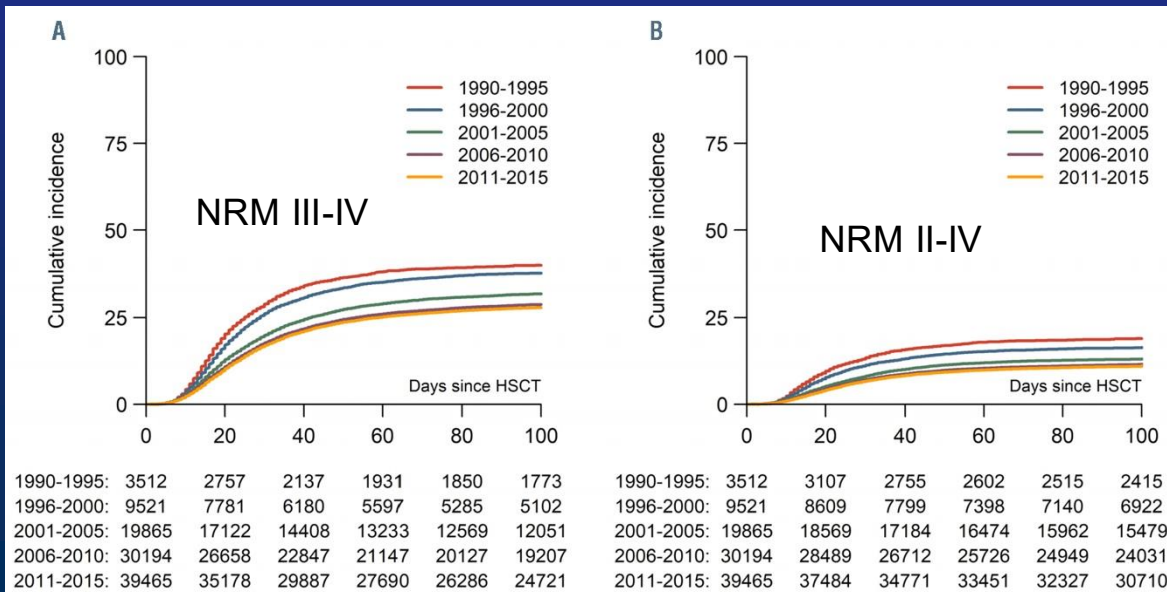
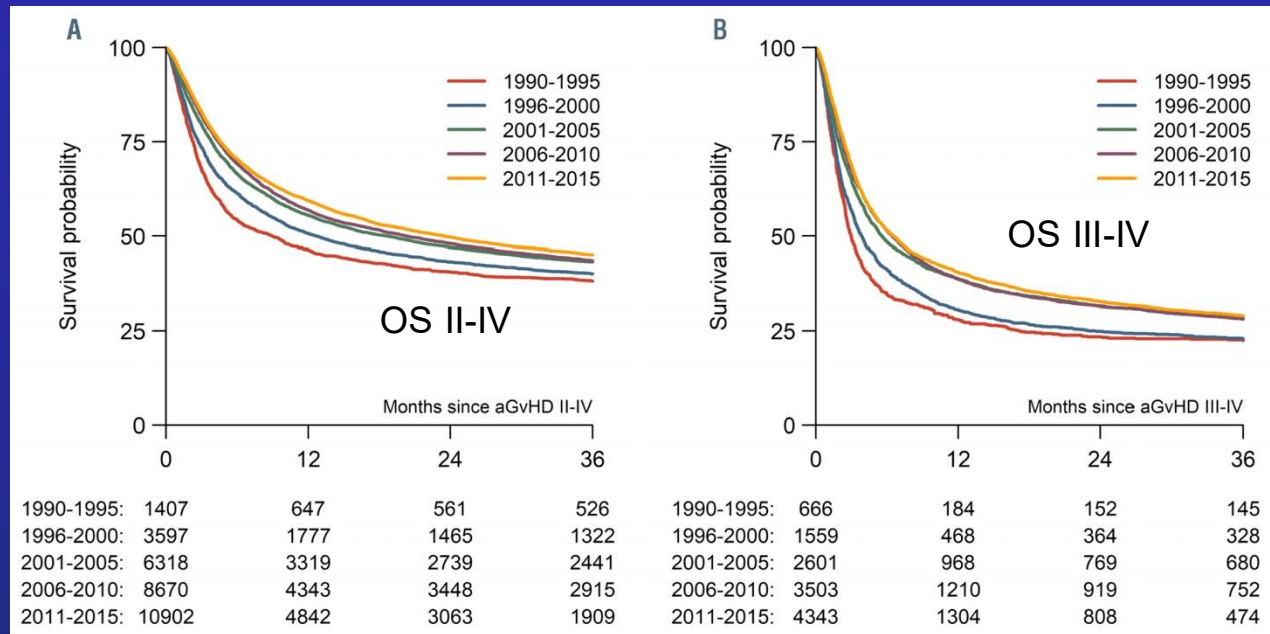
- **Acute and Chronic Graft-versus Host Disease (GvHD) are major complications after allogeneic stem cell transplantation and a major cause for morbidity and mortality after Haploidentical, matched and mismatched unrelated but also after HLA-identical sibling transplantation**

(Kansu et al Blood 2001, Sullivan et al BBMT 1996)

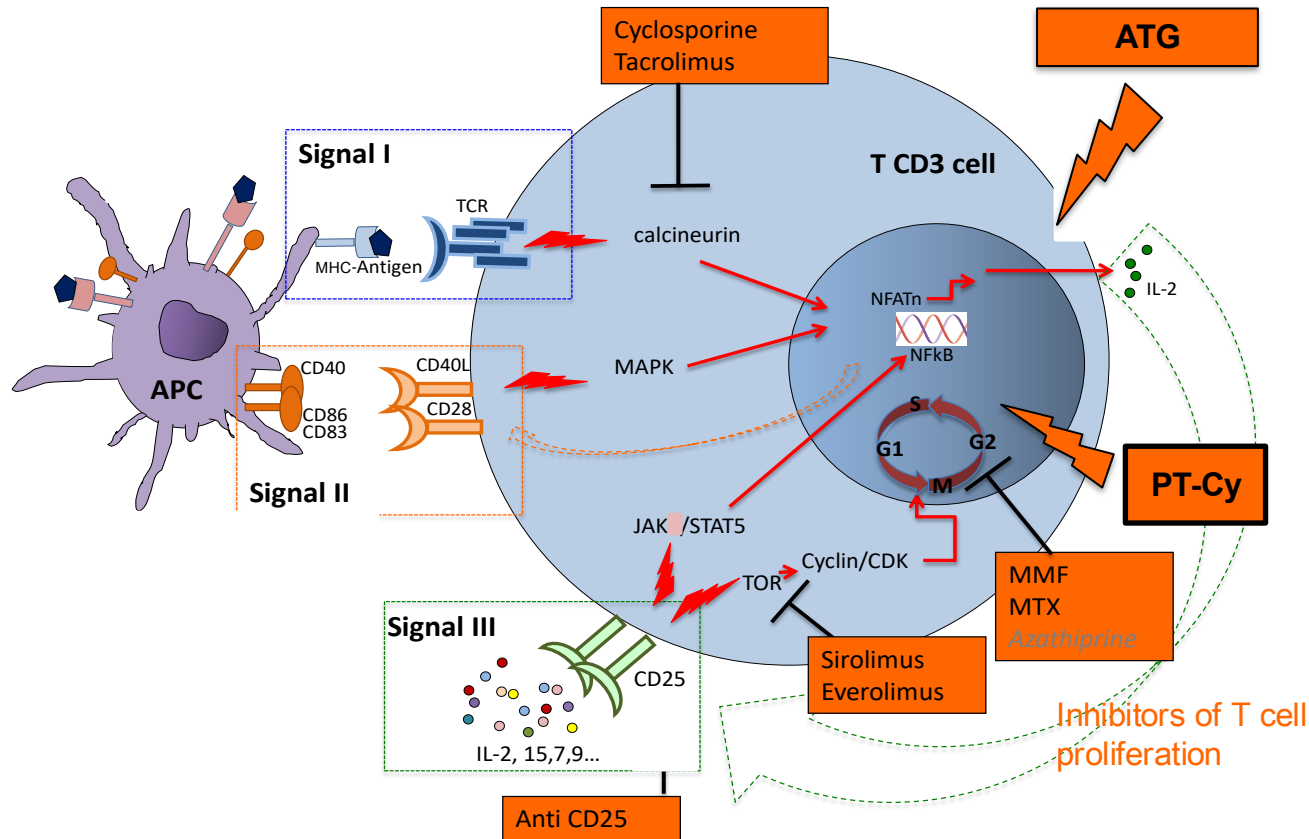
Development of allogeneic SCT in EBMT



Survival in patients with aGvHD (EBMT megafile)

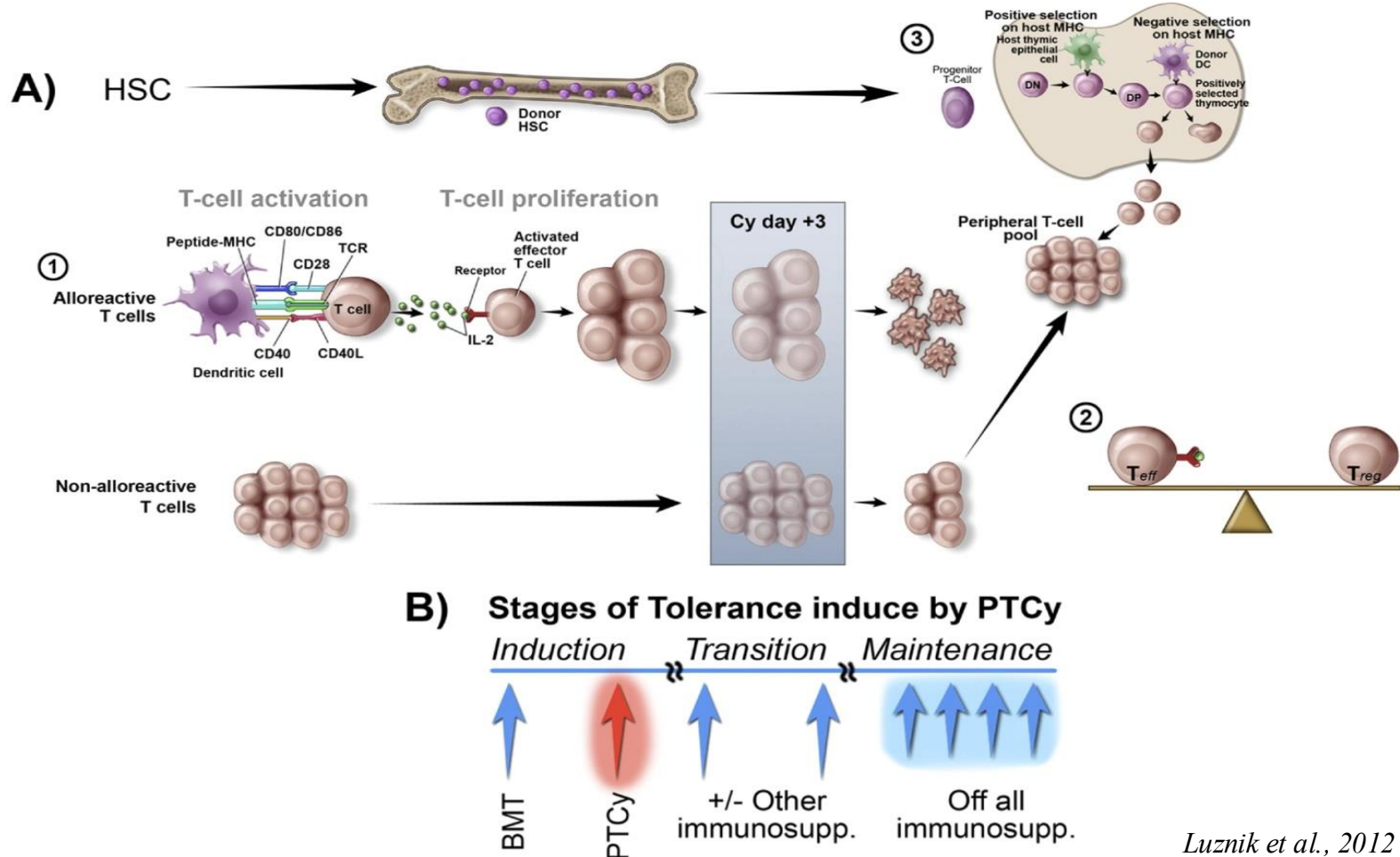


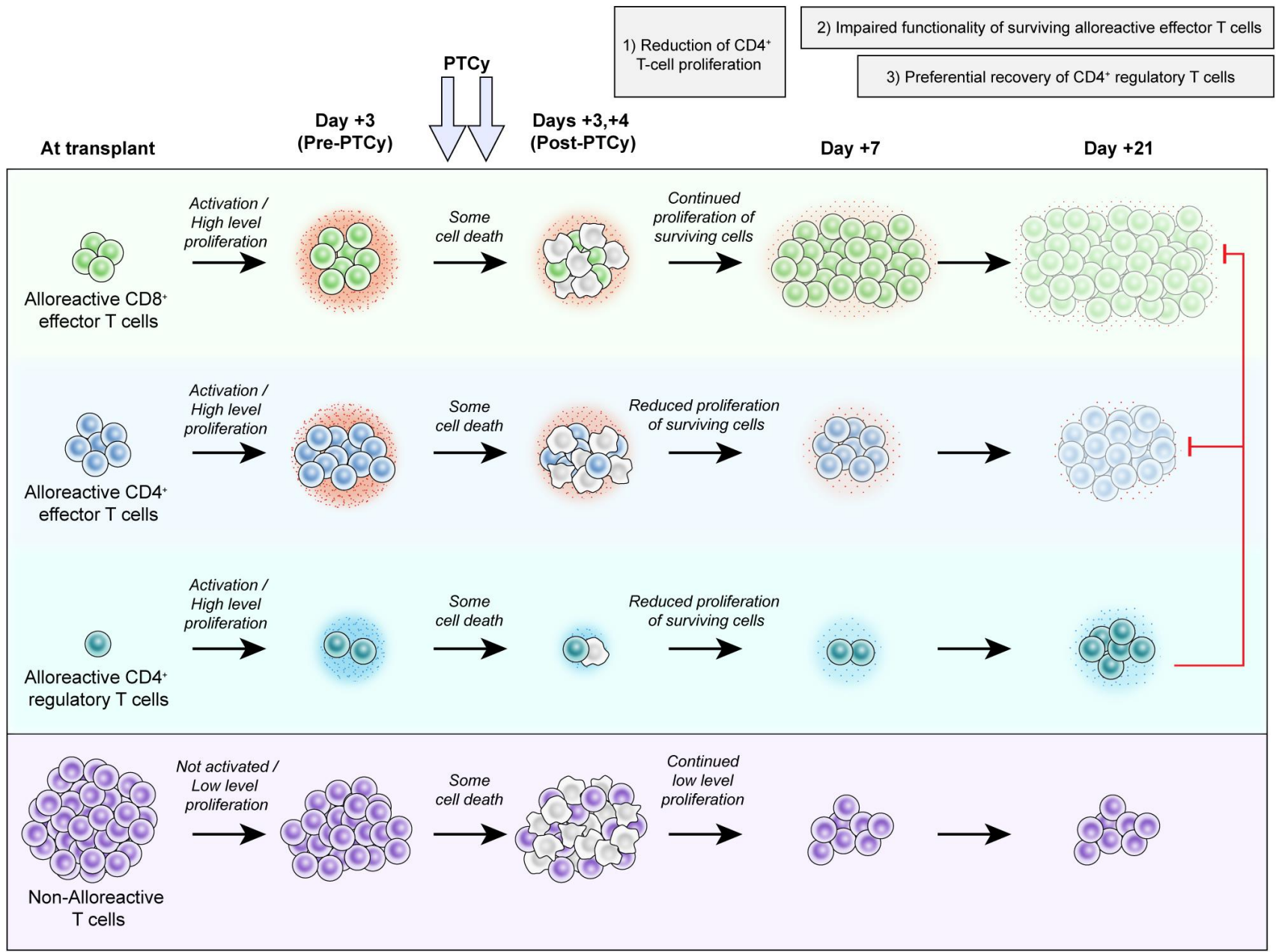
Prevention of GvHD: therapeutic targets



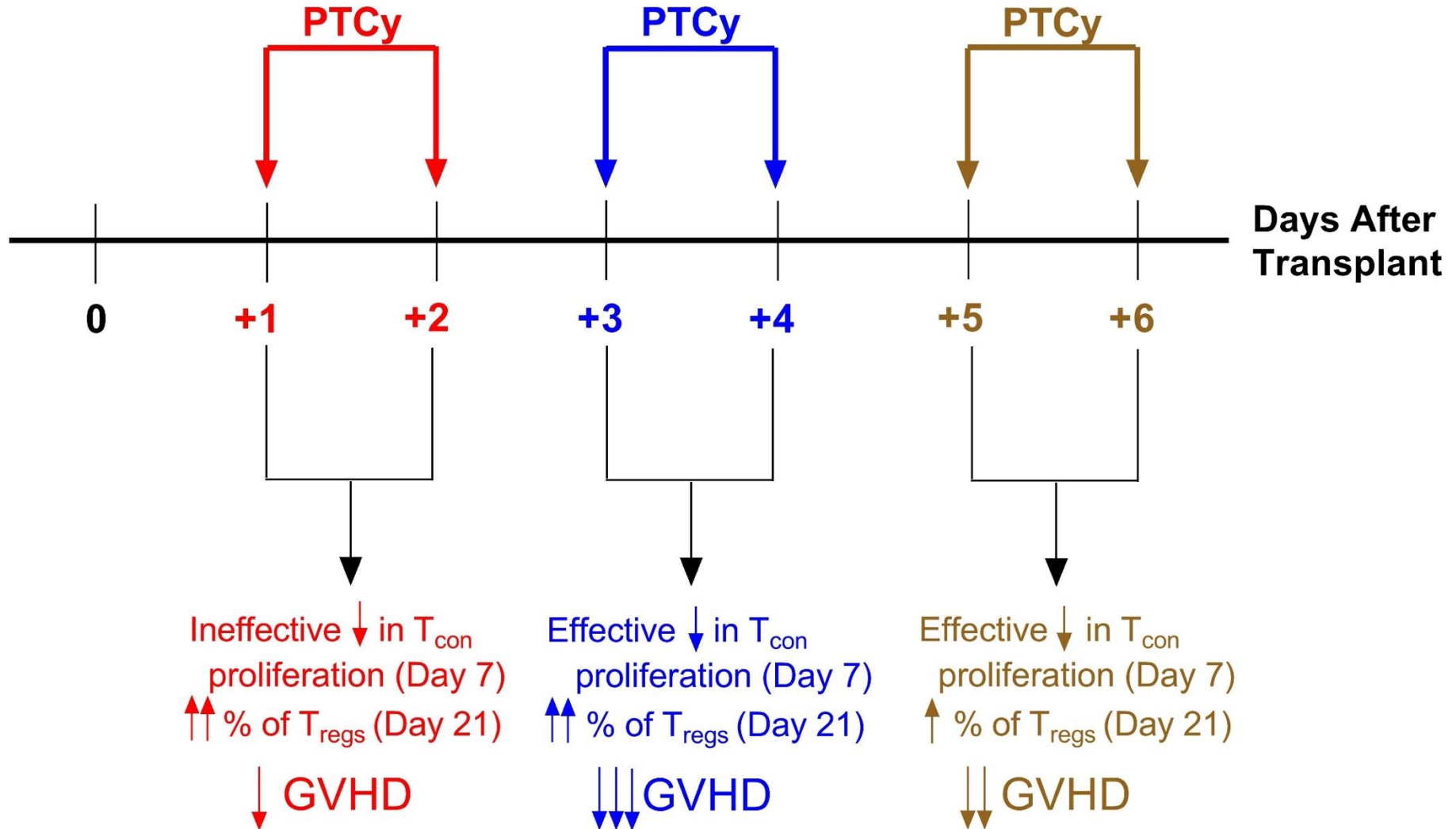
Haplo-identical hematopoietic stem cell transplantation

3. High-dose cyclophosphamide based GvHD prophylaxis

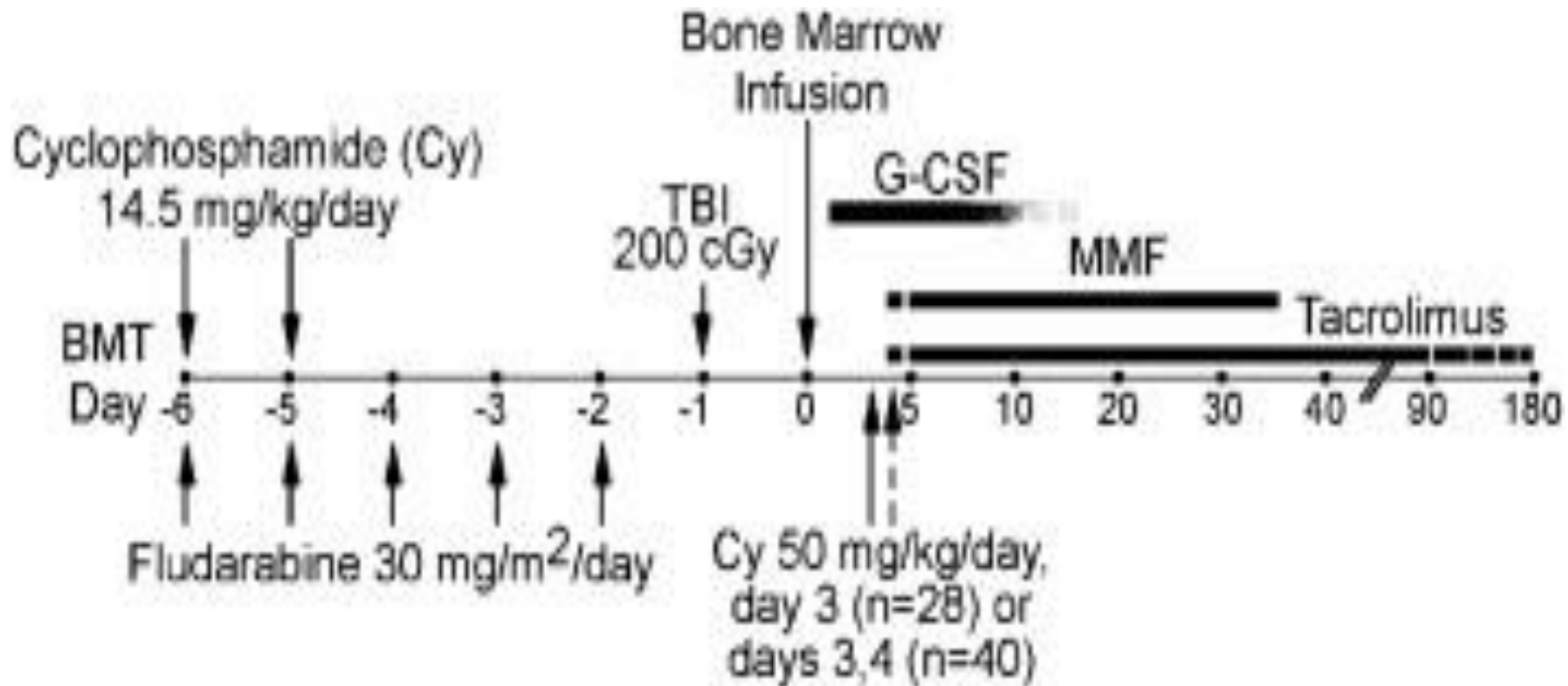




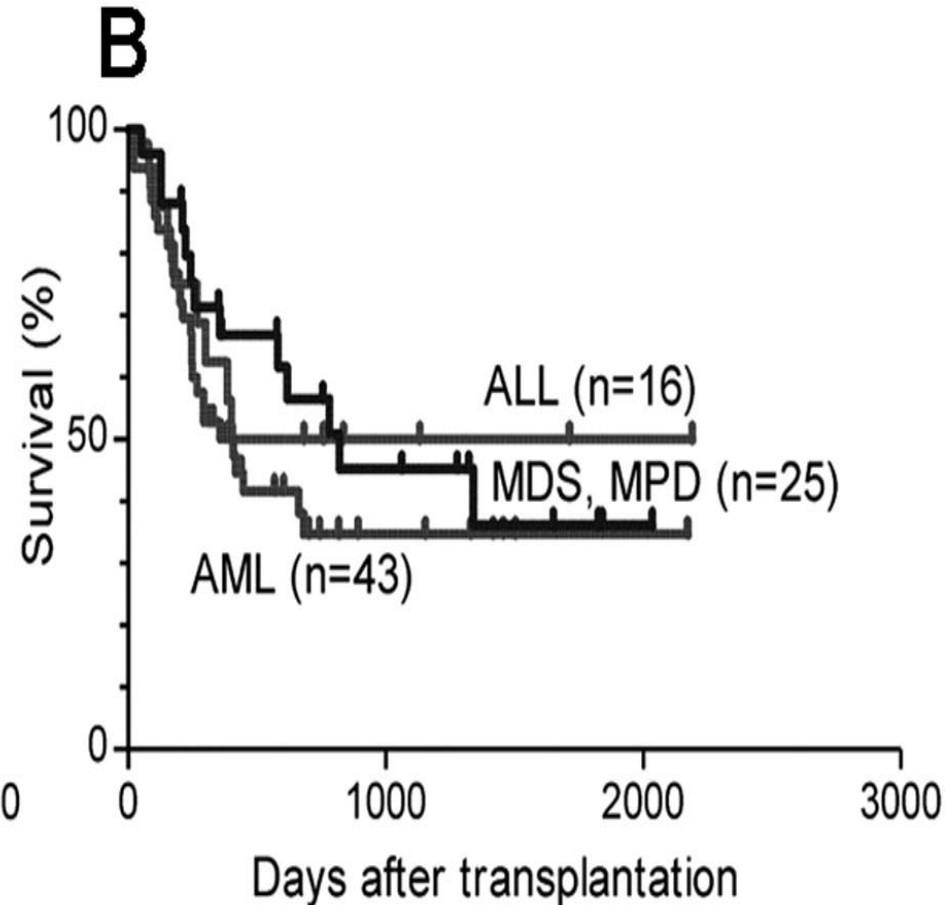
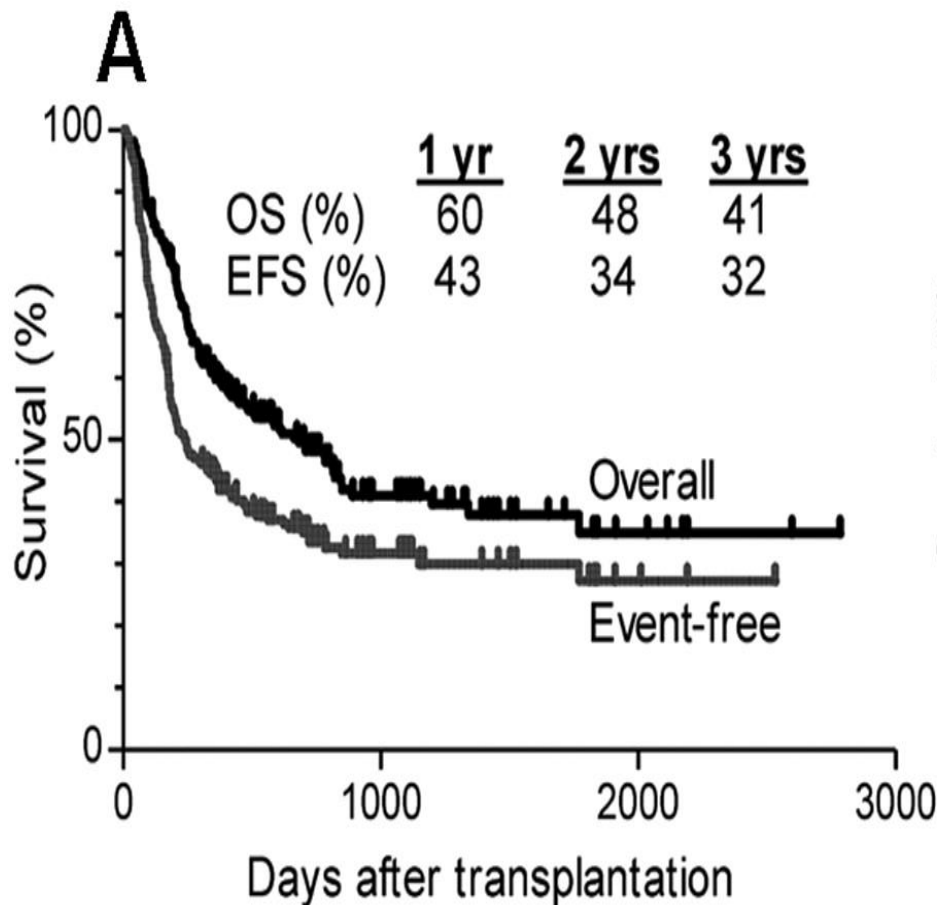
Timing of PTCy



Haplo-identical HSCT using Post-transplant Cyclophosphamide



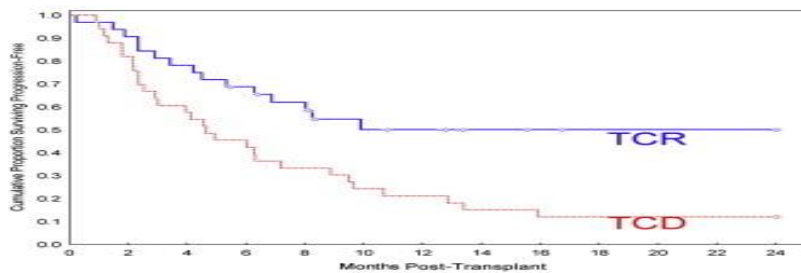
Haplo-identical HSCT with PTCy in after RIC



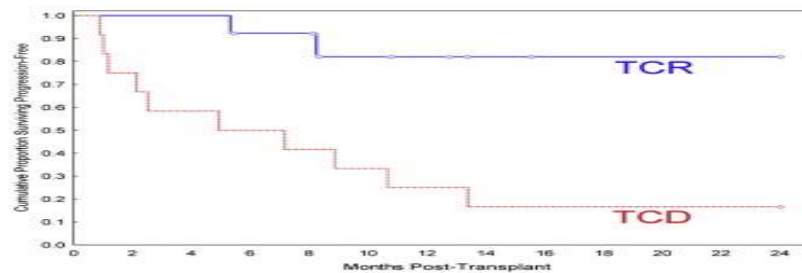
Haplo-identical hematopoietic stem cell transplantation with PTCy vs T-cell depletion

Comparison between TCD or TCR

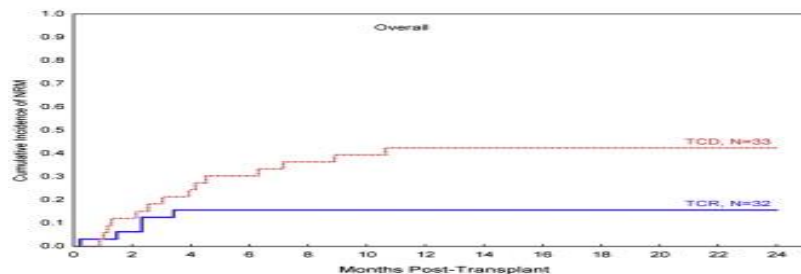
A Progression-free survival for all patients.



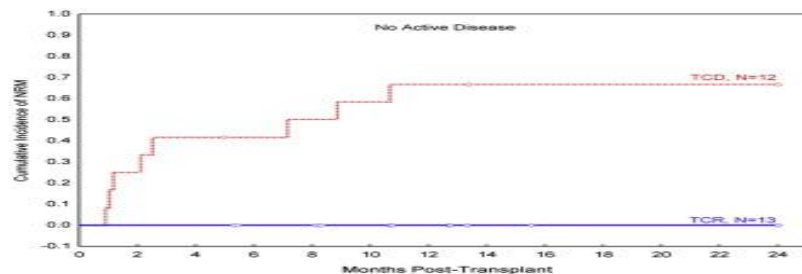
B Progression-free survival for patients in remission at transplant.



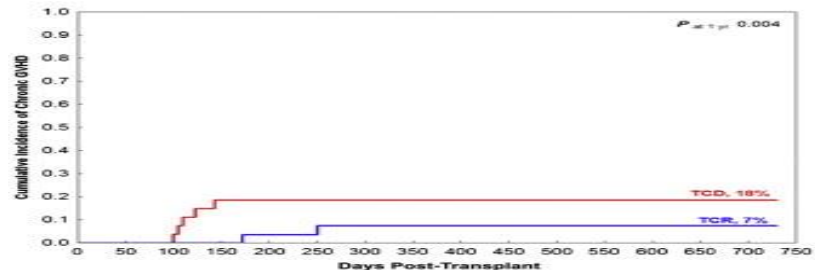
C Non-relapse mortality for all patients.



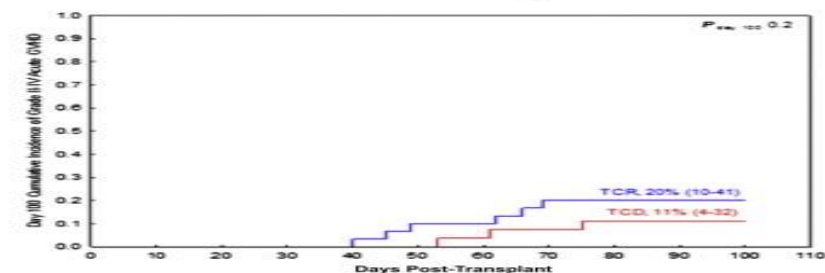
D Non-relapse mortality for patients in remission at transplant.



E Cumulative incidence of cGVHD.

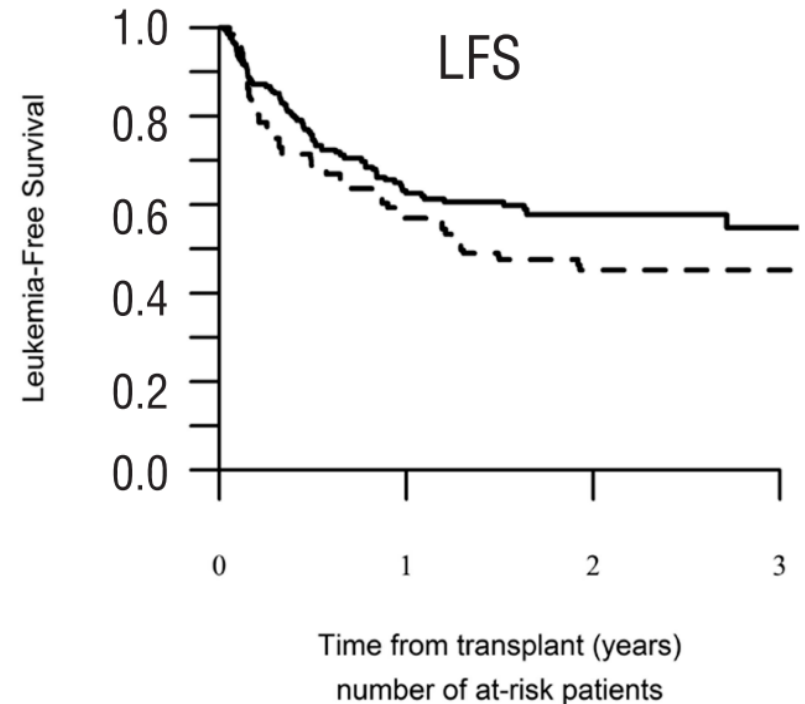
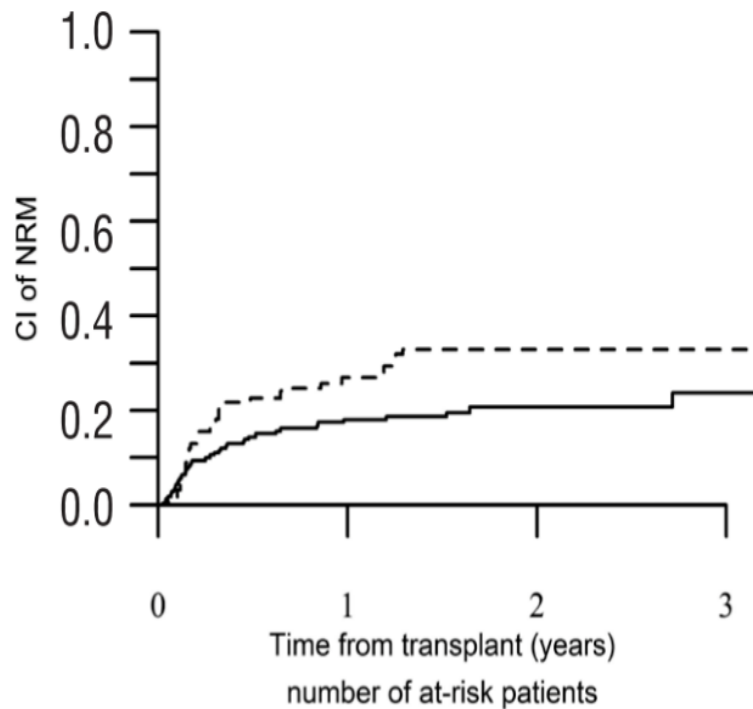


F Cumulative incidence of grade II-IV aGVHD.



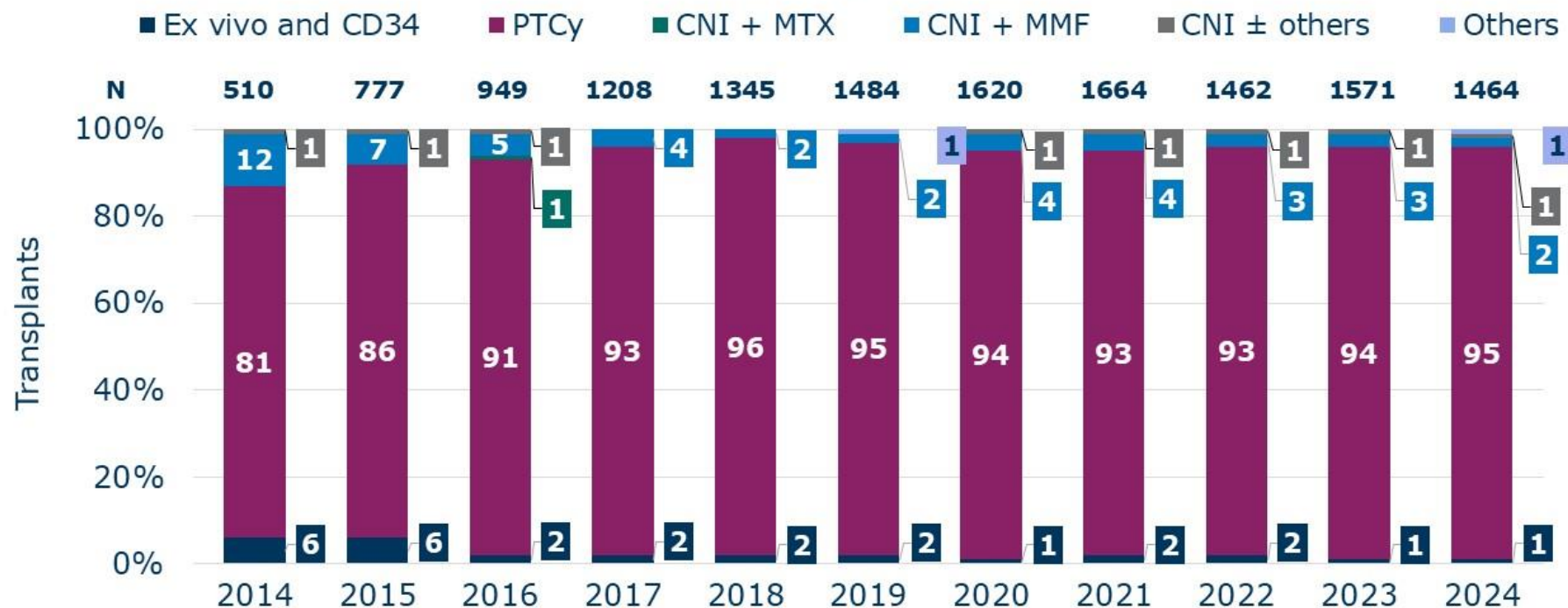
PTCy vs ATG in Haplo HSCT (EBMT)

---- ATG
— PTCy



Increasing use of PTCy in Haplo-identical HSCT (CIBMTR)

GVHD prophylaxis of haplo donor HCTs, US, 2014-2024, adults

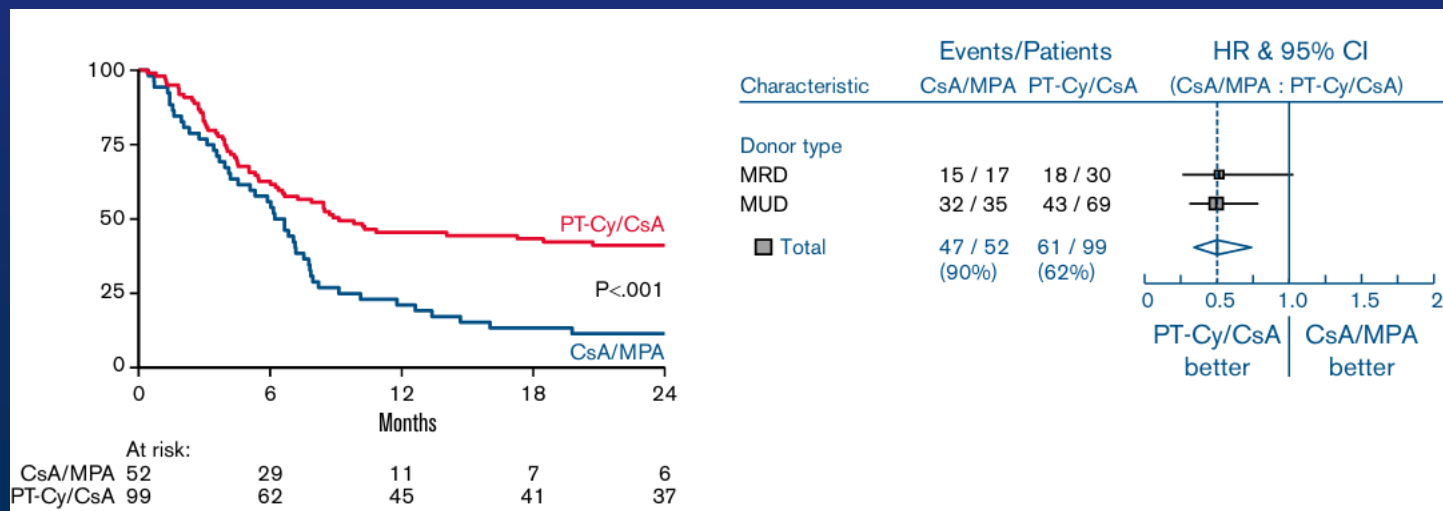
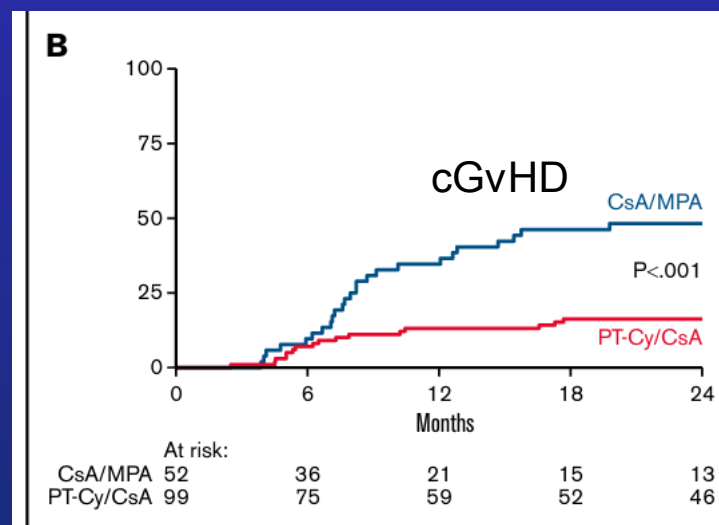
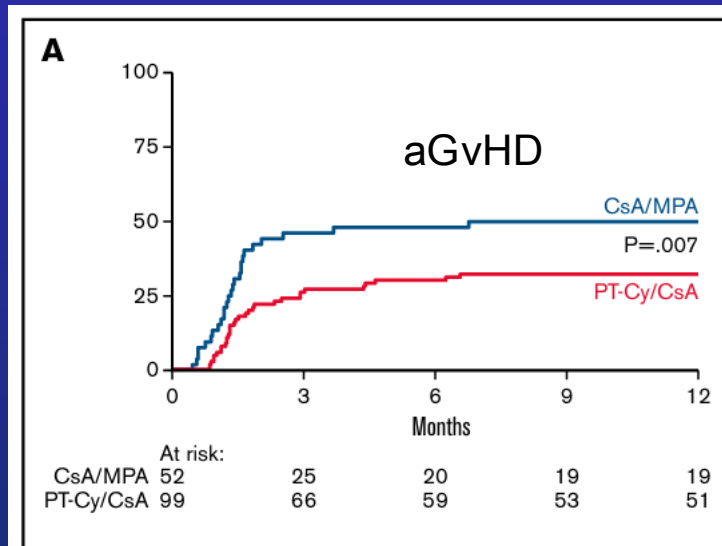


PTCy for matched related and unrelated donors?

Posttransplant cyclophosphamide for prevention of graft-versus-host disease: results of the prospective randomized HOVON-96 trial

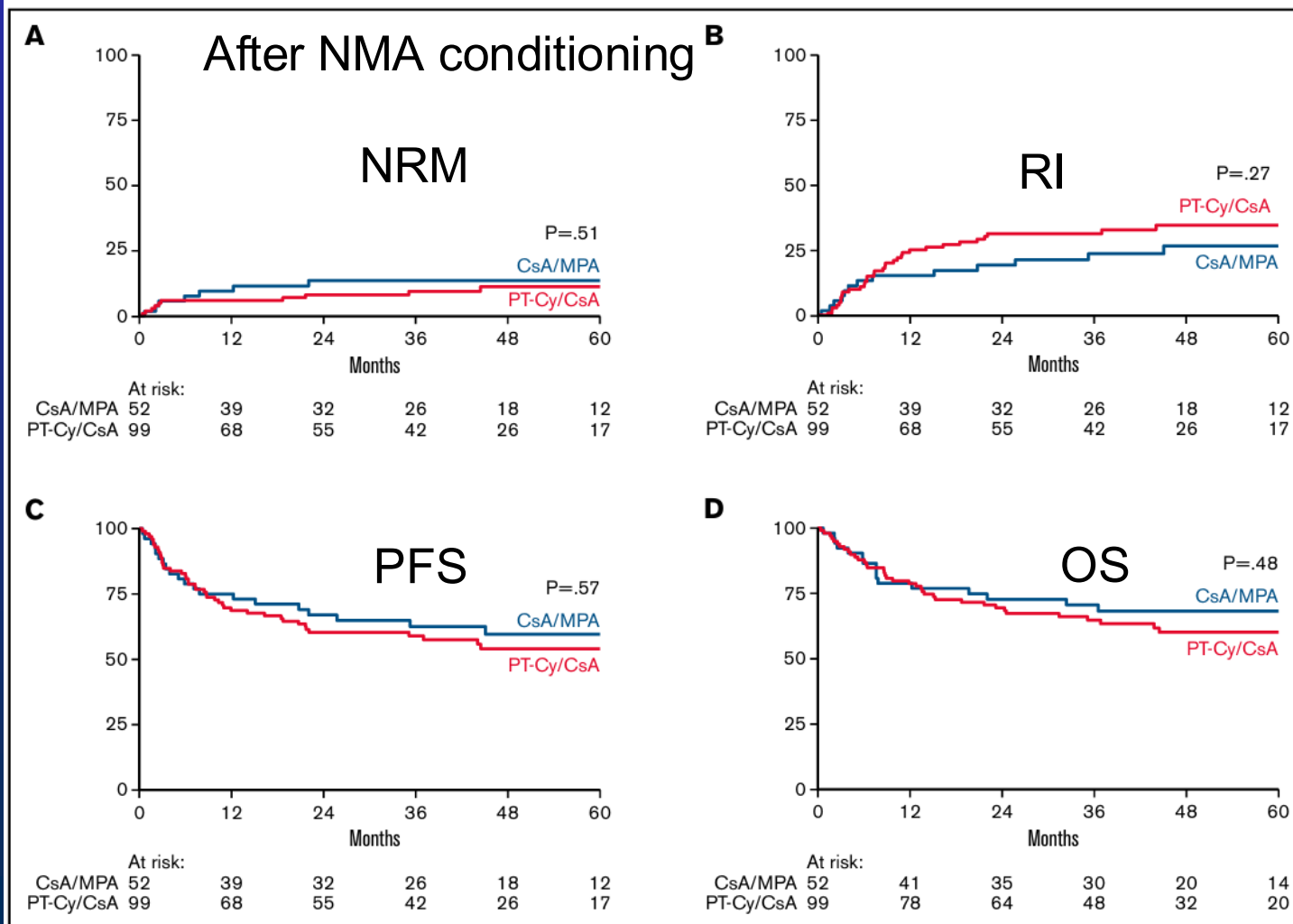
Annoek E. C. Broers,¹ Cornelis N. de Jong,^{1,2} Katerina Bakunina,³ Mette D. Hazenberg,⁴ Marinus van Marwijk Kooy,⁵ Marco R. de Groot,⁶ Michel van Gelder,⁷ Jürgen Kuball,⁸ Bronno van der Holt,³ Ellen Meijer,⁹ and Jan J. Cornelissen,¹ on behalf of the HOVON Stem Cell Transplantation Working Group

NMA

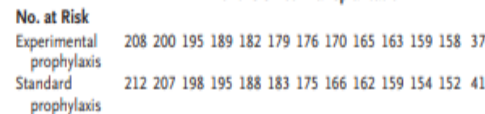
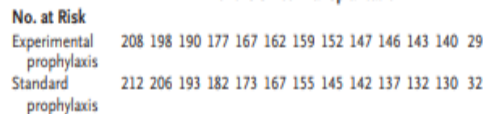
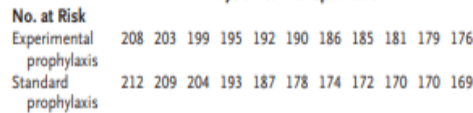


Posttransplant cyclophosphamide for prevention of graft-versus-host disease: results of the prospective randomized HOVON-96 trial

Annoek E. C. Broers,¹ Cornelis N. de Jong,^{1,2} Katerina Bakunina,³ Mette D. Hazenberg,⁴ Marinus van Marwijk Kooy,⁵ Marco R. de Groot,⁶ Michel van Gelder,⁷ Jürgen Kuball,⁸ Bronno van der Holt,³ Ellen Meijer,⁹ and Jan J. Cornelissen,¹ on behalf of the HOVON Stem Cell Transplantation Working Group



TAC/MMF/PTCy vs TAC/MTX after RIC in HLA matched relative and MUD/MMUD



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Post-Transplantation Cyclophosphamide-Based Graft-versus-Host Disease Prophylaxis

J. Bolaños-Meade, M. Hamadani, J. Wu, M.M. Al Malki, M.J. Martens, L. Runaas, H. Elmariah, A.R. Rezvani, M. Gooptu, K.T. Larkin, B.C. Shaffer, N. El Jurdi, A.W. Loren, M. Solh, A.C. Hall, A.M. Alousi, O.H. Jamy, M.-A. Perales, J.M. Yao, K. Applegate, A.S. Bhatt, L.S. Kean, Y.A. Efebera, R. Reshef, W. Clark, N.L. DiFronzo, E. Leifer, M.M. Horowitz, R.J. Jones, and S.G. Holtan, for the BMT CTN 1703 Investigators*

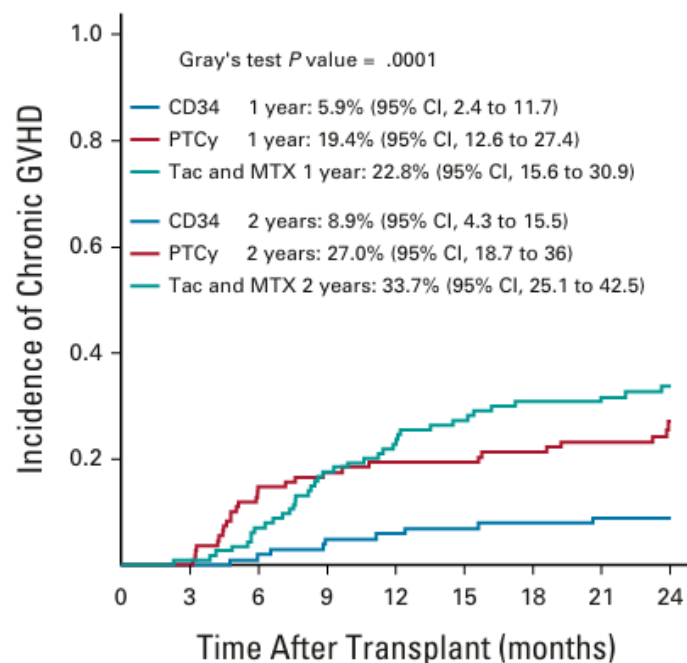
A Adjusted GVHD-free, Relapse-free Survival



*Bolanos –Meade
et al NEJM 2024*

Randomized Phase III BMT CTN Trial of Calcineurin Inhibitor–Free Chronic Graft-Versus-Host Disease Interventions in Myeloablative Hematopoietic Cell Transplantation for Hematologic Malignancies

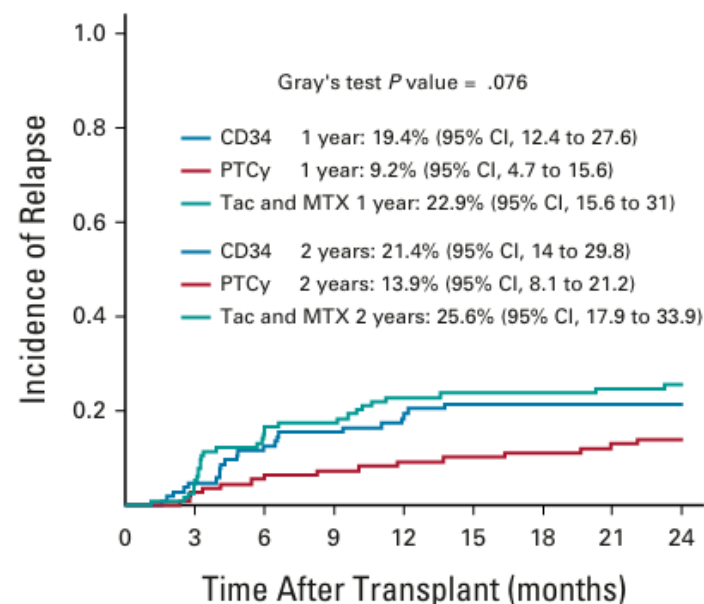
Leo Luznik, MD¹; Marcelo C. Pasquini, MD, MS²; Brent Logan, PhD²; Robert J. Soiffer, MD³; Juan Wu, PhD⁴; Steven M. Devine, MD⁵; Nancy Geller, PhD⁶; Sergio Giralt, MD⁷; Helen E. Heslop, MD⁸; Mary M. Horowitz, MD, MS²; Richard J. Jones, MD¹; Mark R. Litzow, MD⁹; Adam Mendizabal, PhD⁴; Lori Muffly, MD¹⁰; Eneida R. Nemecek, MD¹¹; Lynn O'Donnell, PhD¹²; Richard J. O'Reilly, MD⁷; Raquel Palencia, PharmD¹³; Johannes Schetelig, MD¹³; Leyla Shune, MD¹⁴; Scott R. Solomon, MD¹⁵; Sumithira Vasu, MD¹²; Vincent T. Ho, MD³; and Miguel-Angel Perales, MD⁷



No. at risk:

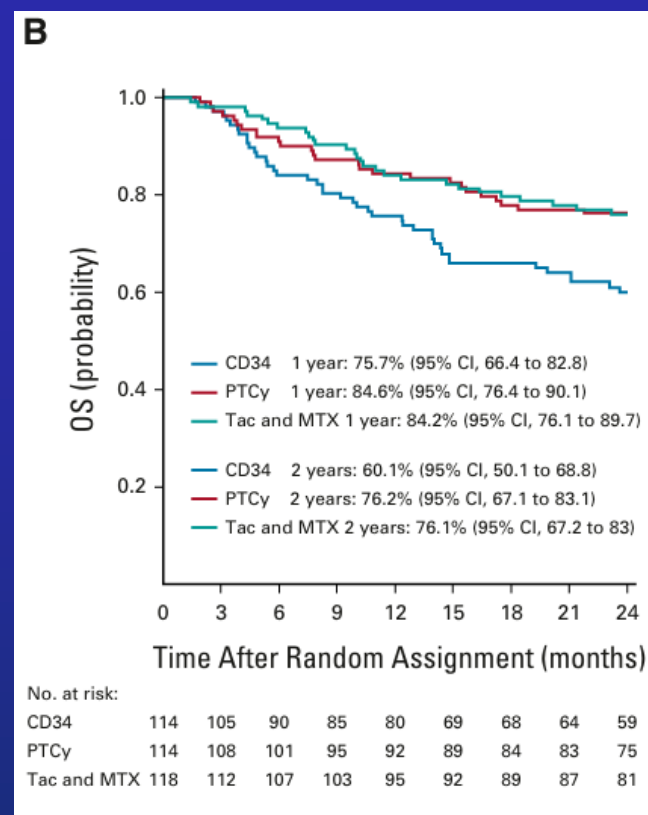
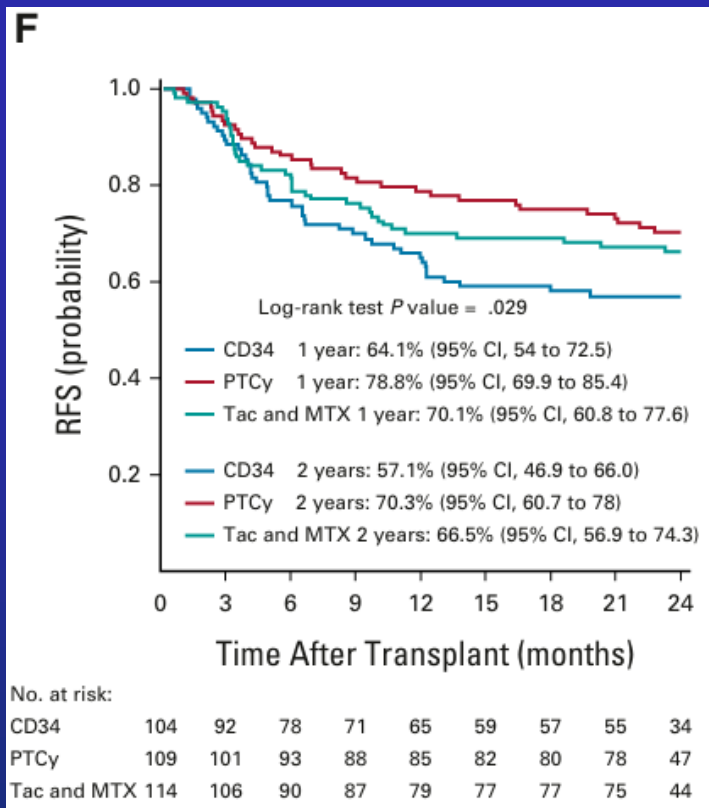
CD34	104	97	84	76	71	64	61	57	34
PTCy	109	104	82	74	70	67	62	60	31
Tac and MTX	114	111	98	82	71	64	57	54	28

E



No. at risk:

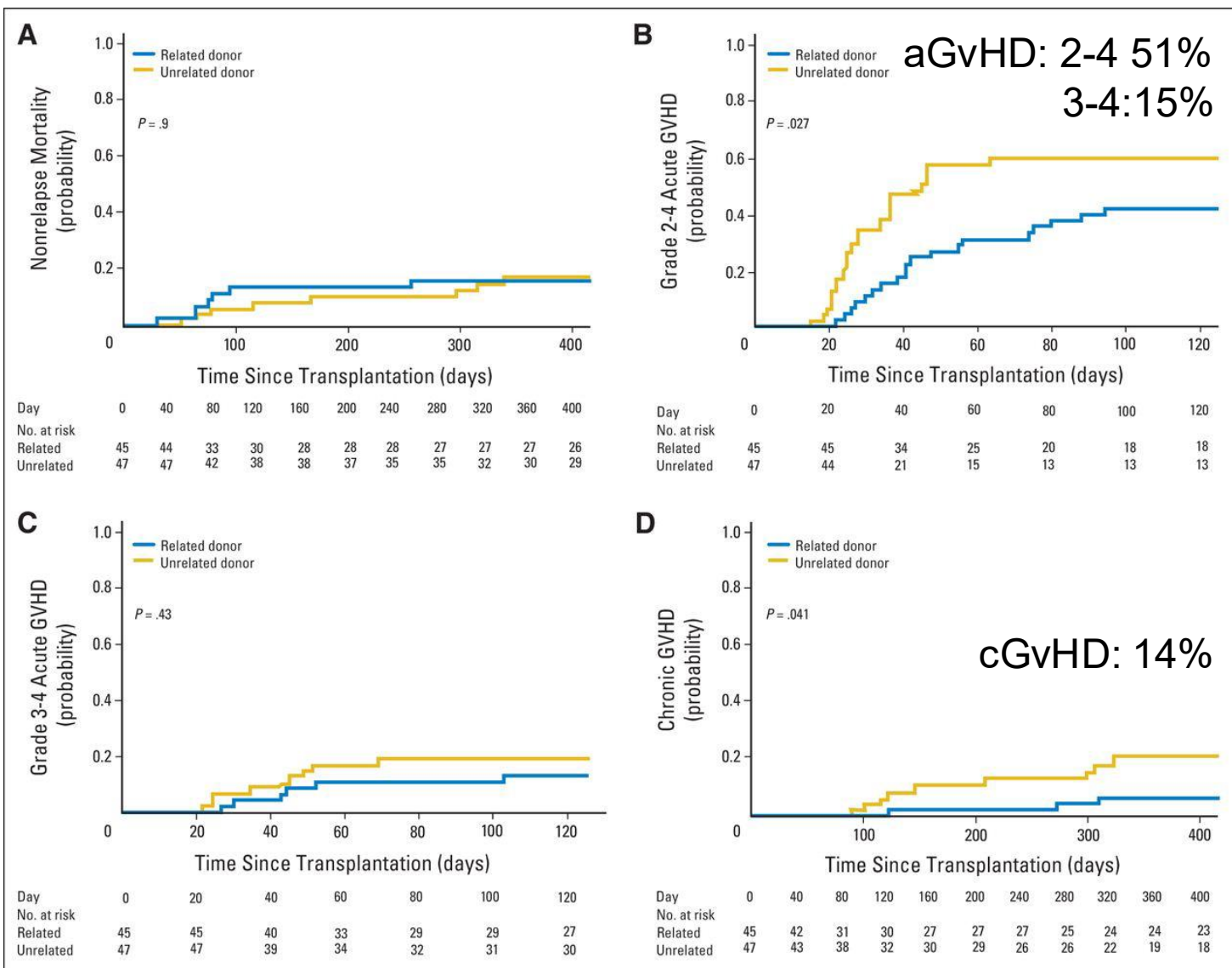
CD34	104	92	78	71	65	59	57	55	34
PTCy	109	101	93	88	85	82	80	78	47
Tac and MTX	114	106	90	87	79	77	77	75	44



CD34 selection resulted in lower rates of chronic GVHD but was associated with worse survival compared with the other interventions.

Post-transplant cyclophosphamide without CNl was not superior to tacrolimus and methotrexate with BM in relation to chronic GVHD and survival

PTCy (50 mg/kg on day +3 and +4) as single GvHD Prophylaxis after MRD (n= 45) and MUD (n=47) after MAC (Bu/Flu) and BM



ORIGINAL ARTICLE

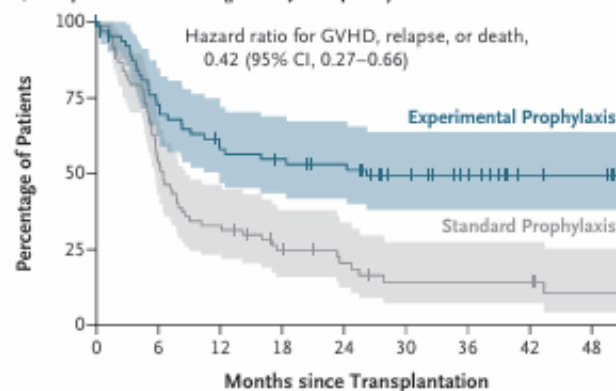
Graft-versus-Host Disease Prophylaxis with Cyclophosphamide and Cyclosporin

D.J. Curtis,^{1,2} S.S. Patil,¹ J. Reynolds,^{1,2} D. Purtill,³ C. Lewis,⁴ D.S. Ritchie,⁵ D.J. Gottlieb,⁶⁻⁸
 D.T. Yeung,⁹ E. Wong,¹⁰ S.-K. Tey,¹¹⁻¹³ T. Perera,¹⁴ J. Moore,¹⁵ R.M. Koldej,¹⁶
 R. De Abreu Lourenco,¹⁷ J. Stubbs,¹⁸ C.O. Morrissey,¹⁹ N. Munsef,¹⁸ A. Arenas,¹⁸
 and G.R. Hill,^{13,20,21} for the Australasian Leukaemia and Lymphoma Group*

End Point	Experimental Prophylaxis (N = 66)	Standard Prophylaxis (N = 68)
Grade III or IV acute GVHD (95% CI) — %†		
At 3 mo	3 (1–10)	10 (4–19)
At 6 mo	6 (2–14)	18 (10–28)
Moderate-to-severe chronic GVHD (95% CI) — %†		
At 12 mo	14 (7–24)	24 (14–35)
At 24 mo	18 (9–28)	33 (21–45)
Immunosuppression-free survival at 12 mo (95% CI) — %‡	54 (42–67)	31 (20–43)
Relapse (95% CI) — %†		
At 12 mo	14 (7–24)	18 (10–28)
At 24 mo	16 (8–26)	21 (12–32)

PTCy as GvHD prophylaxis in HLA-ident Sibling HSCT

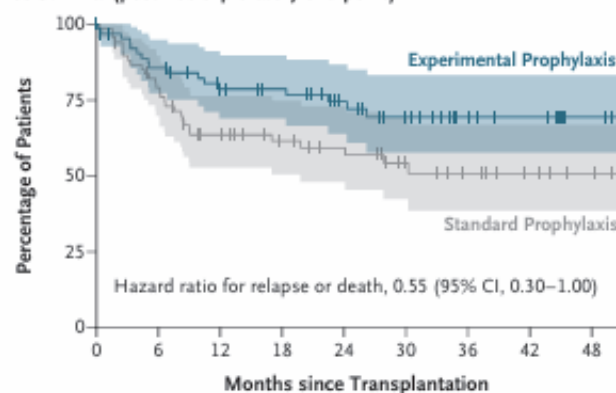
A GVHD-free, Relapse-free Survival (primary end point)



No. at Risk

Experimental prophylaxis	66	45	35	32	29	21	16	7	6
Standard prophylaxis	68	36	22	14	10	6	6	6	3

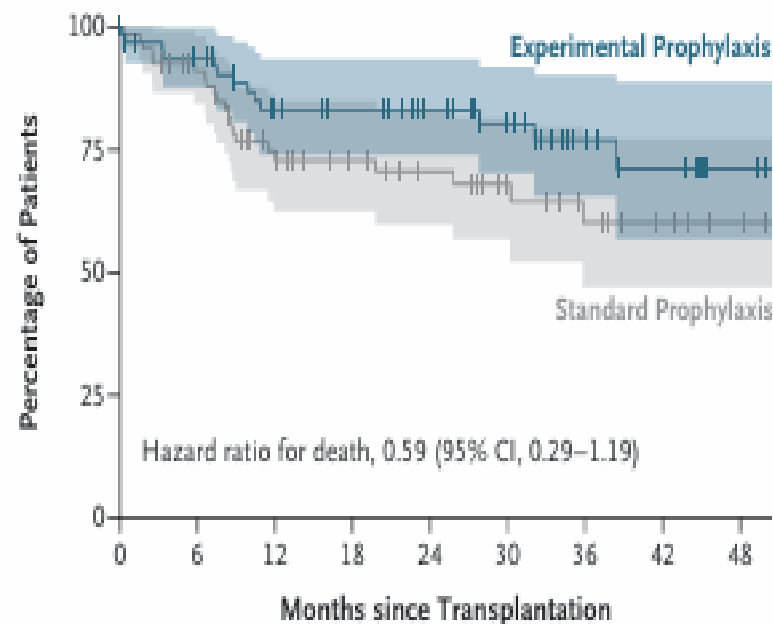
B Relapse-free Survival (post hoc exploratory end point)



No. at Risk

Experimental prophylaxis	66	53	43	40	30	23	15	11	5
Standard prophylaxis	68	52	36	29	25	16	12	8	5

C Overall Survival (secondary end point)

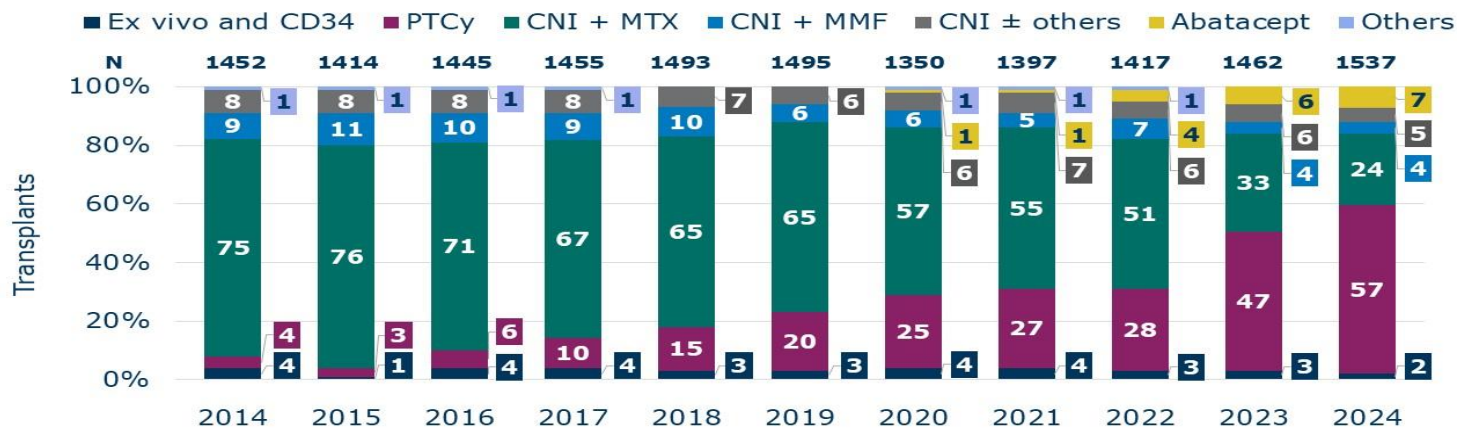


No. at Risk

Experimental prophylaxis	66	57	44	41	33	26	16	11	5
Standard prophylaxis	68	58	39	33	28	19	14	10	6

Increasing use of PTCy in unrelated HSCT (CIBMTR)

GVHD prophylaxis of MUD HCTs, US, 2014-2024, adults, MAC

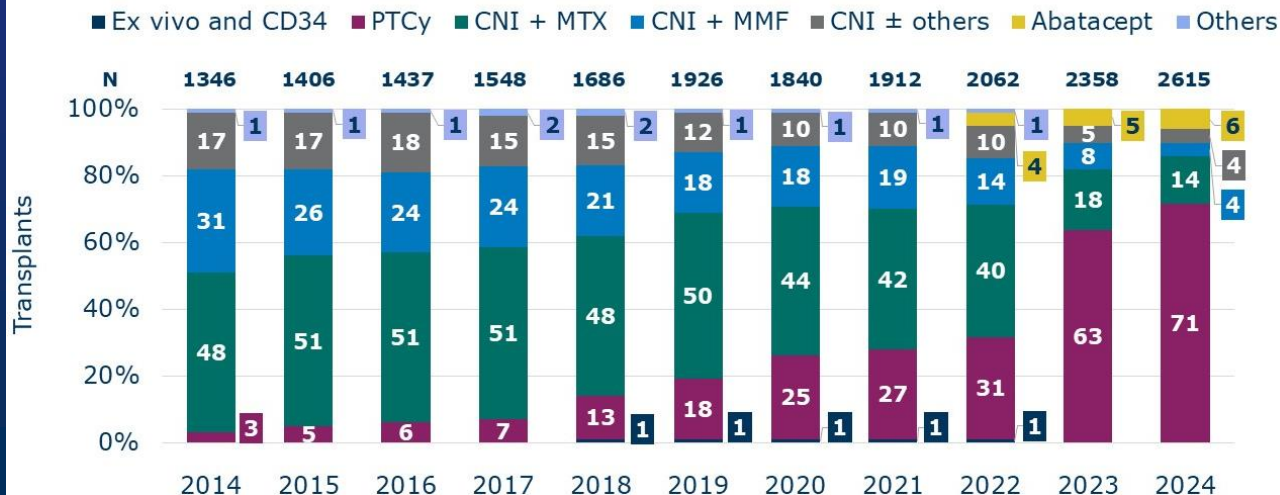


Abbreviations: CNI, calcineurin inhibitor; ex vivo and CD34, ex vivo T cell depletion and CD34-selected grafts; GVHD, graft-versus-host disease; HCT, hematopoietic cell transplantation; MAC, myeloablative conditioning; MMF, mycophenolate mofetil; MTX, methotrexate; MUD, matched unrelated donor; PTCy, post-transplant cyclophosphamide.

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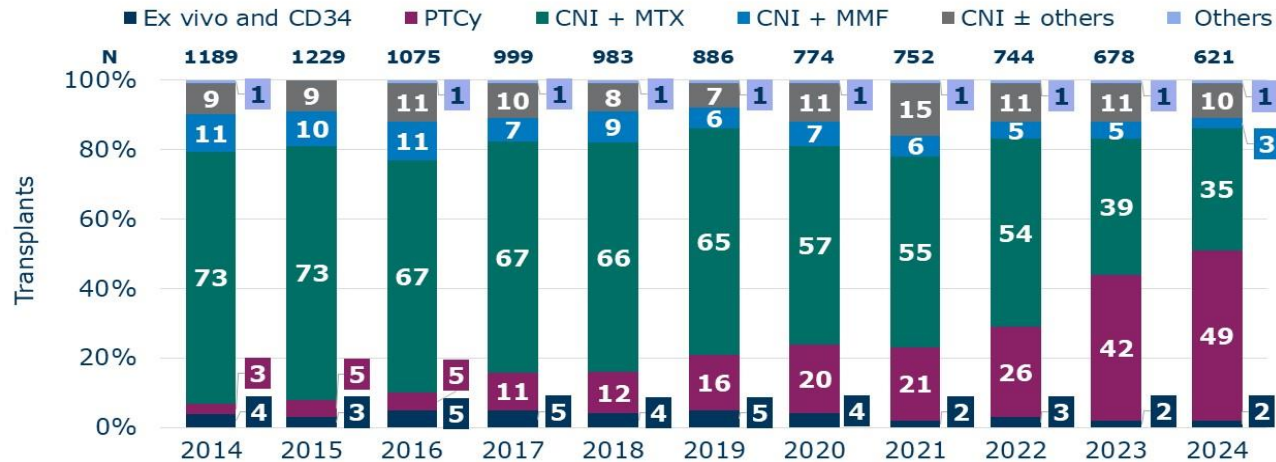
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GVHD prophylaxis of MUD HCTs, US, 2014-2024, adults, RIC/NMA



Increasing use of PTCy in HLA-identical sibling (CIBMTR)

GVHD prophylaxis, MRD HCTs, US, 2014-2024, adults, MAC

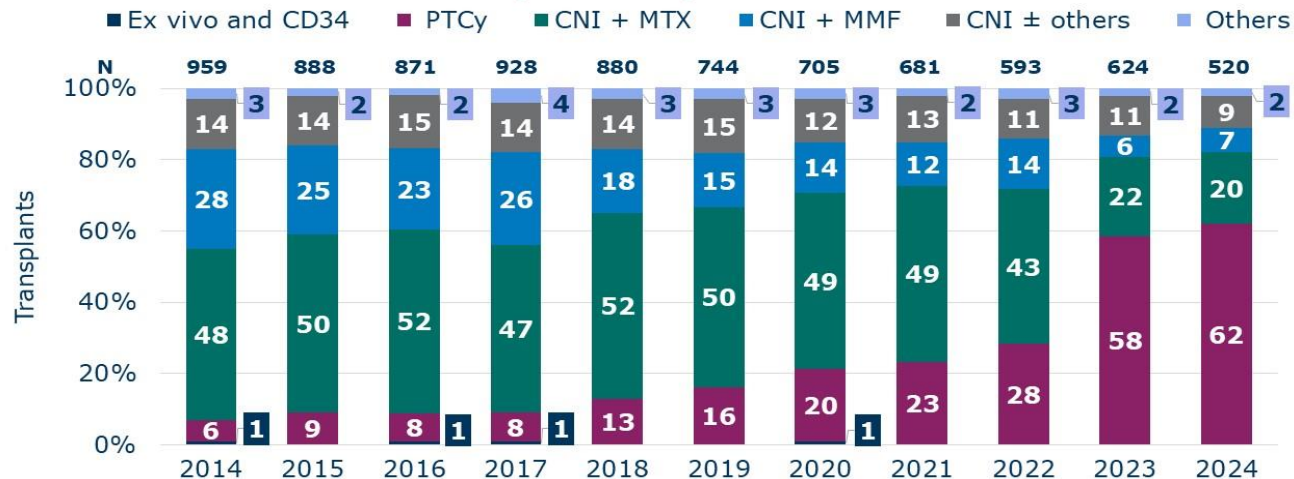


Abbreviations: CNI, calcineurin inhibitor; ex vivo and CD34, ex vivo T cell depletion and CD34-selected grafts; GVHD, graft-versus-host disease; HCT, hematopoietic cell transplantation; MAC, myeloablative conditioning; MMF, mycophenolate mofetil; MRD, matched related donor; MTX, methotrexate, PTCy, post-transplant cyclophosphamide.

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GVHD prophylaxis of MRD HCTs, US, 2014-2024, adults, RIC/NMA

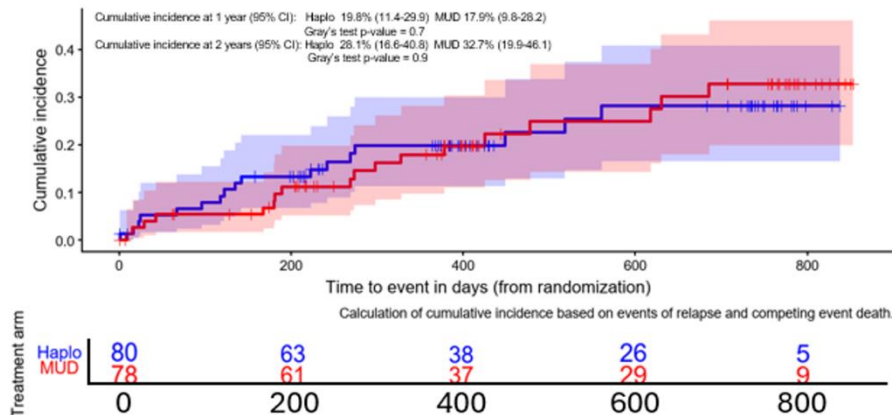


Randomized European Study Haplo vs MUD with PTCy

A

CIR in ITT

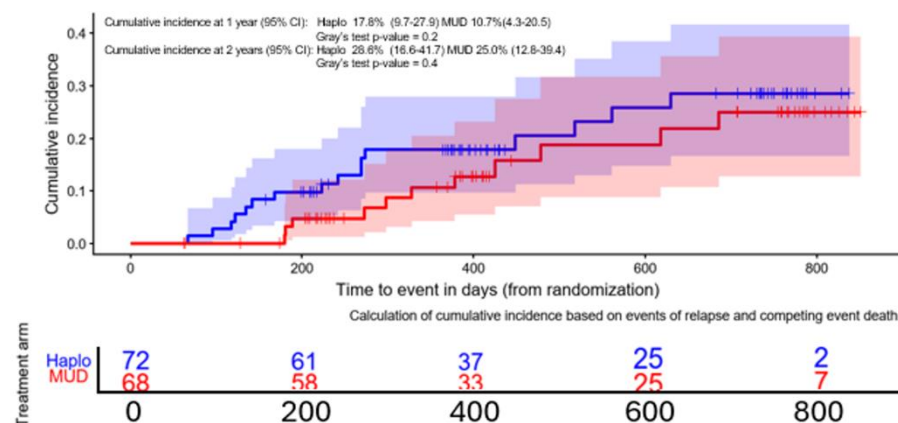
Treatment arm Haplo MUD



B

CIR in PPP

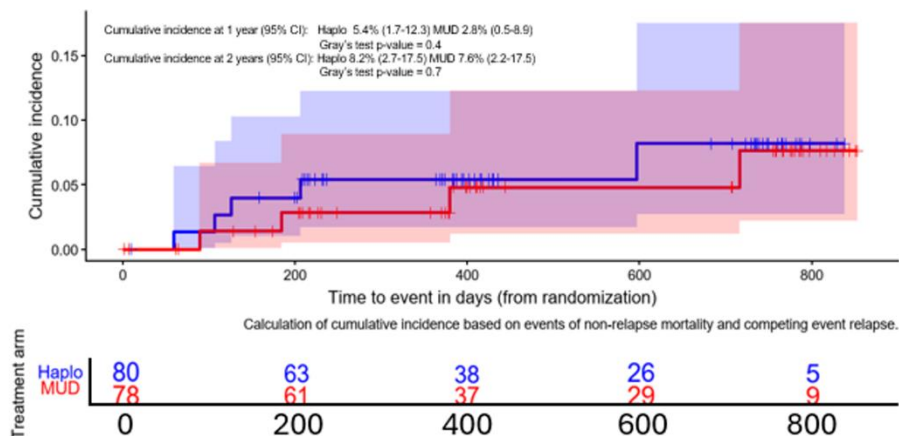
Treatment arm Haplo MUD



C

NRM in ITT

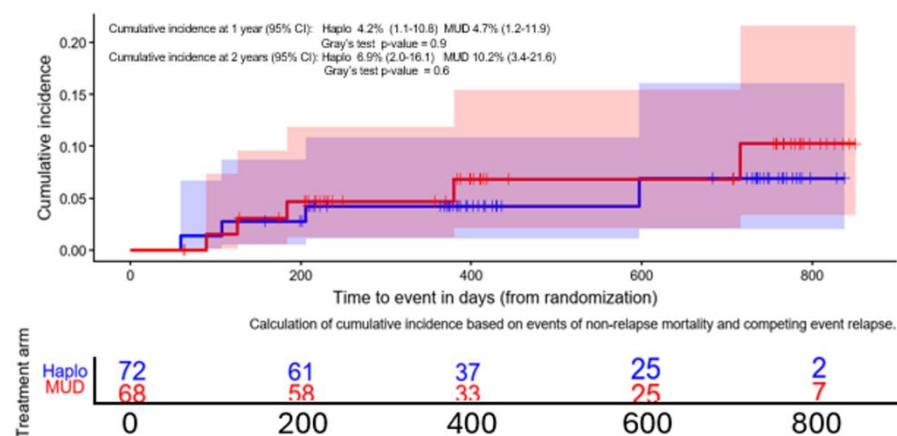
Treatment arm Haplo MUD



D

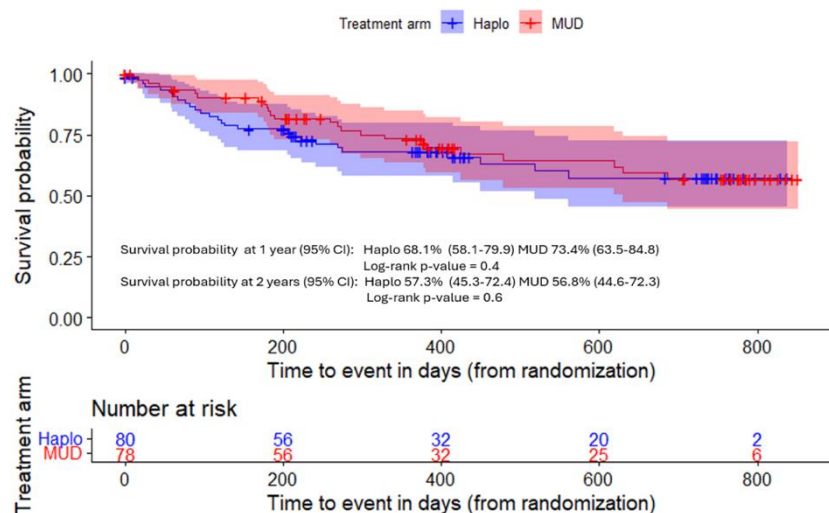
NRM in PPP

Treatment arm Haplo MUD

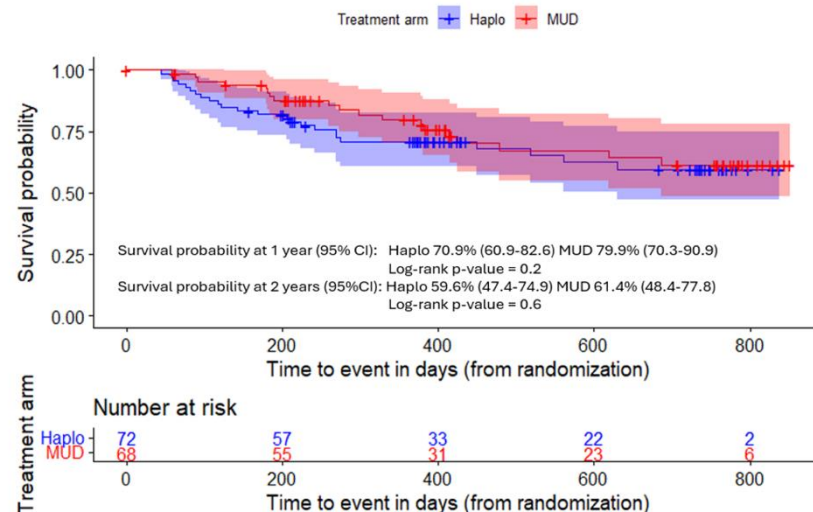


Randomized European Study Haplo vs MUD with PTCy

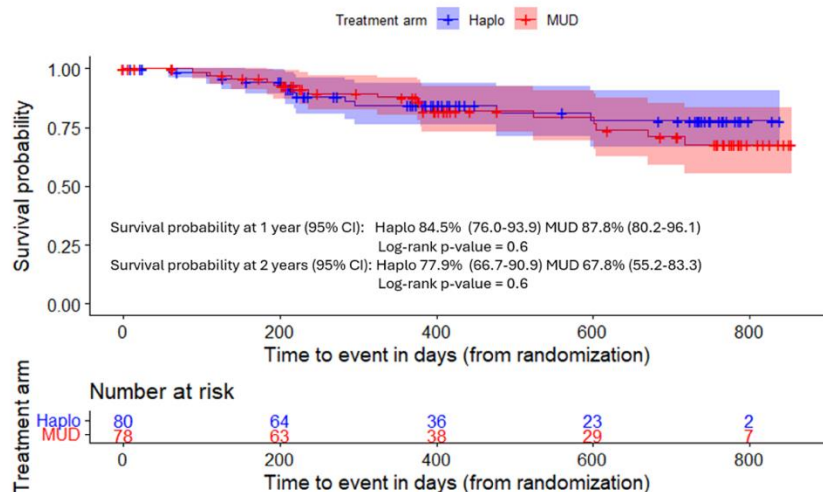
E GRFS in ITT



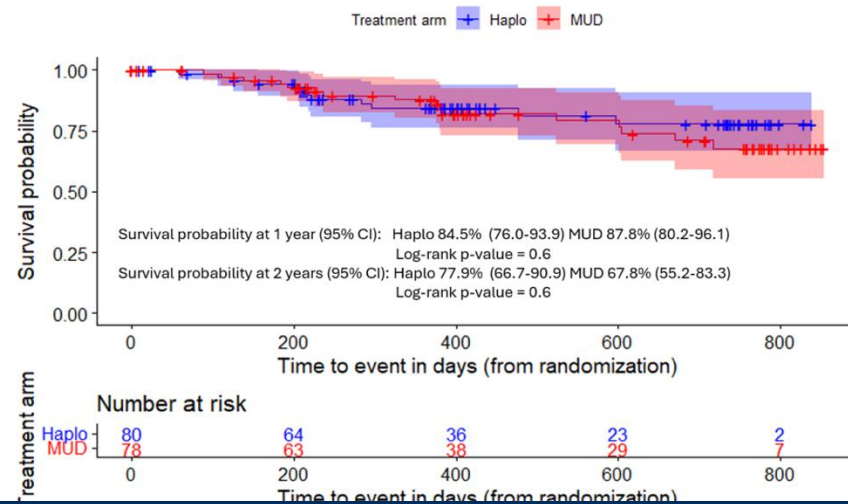
F GRFS in PPP



C OS in ITT



D OS in PPP

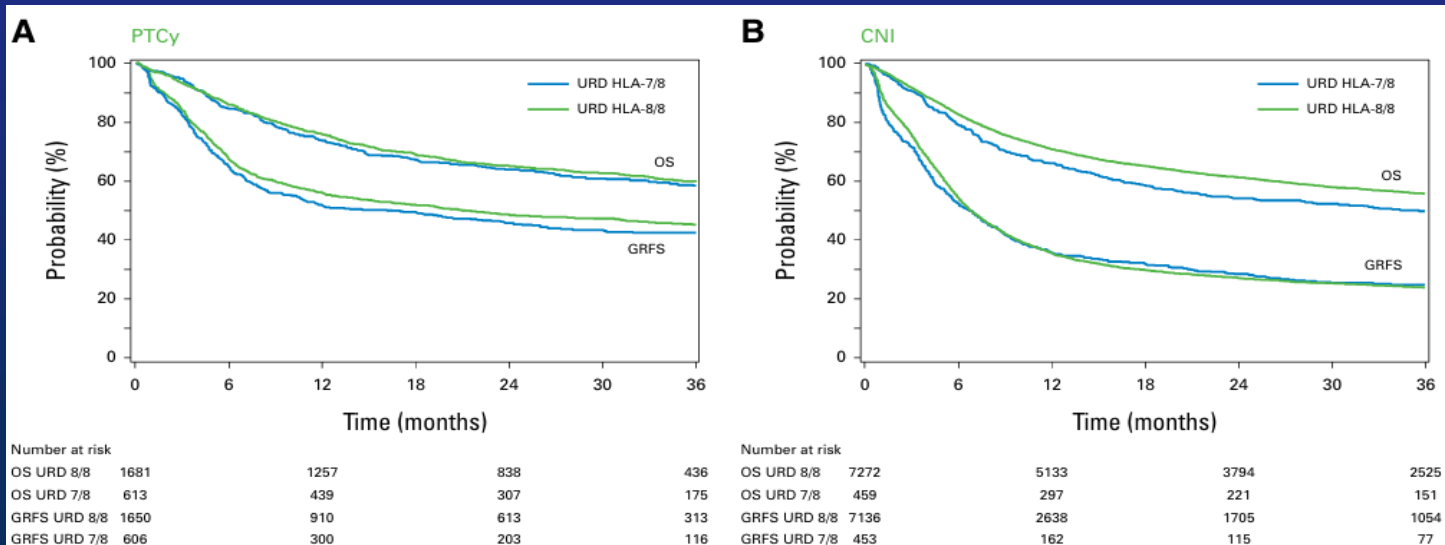


PTCy for mismatched unrelated donors (MMUD)?

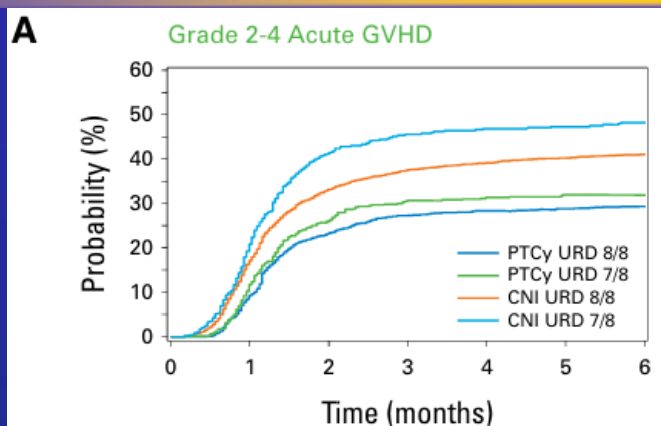
⑥ Post-Transplant Cyclophosphamide–Based Graft-Versus-Host Disease Prophylaxis Attenuates Disparity in Outcomes Between Use of Matched or Mismatched Unrelated Donors

Brian C. Shaffer, MD, MS¹ ; Mahasweta Gooptu, MD²; Todd E. DeFor, MS³; Martin Maiers, MS³ ; Javier Bolaños-Meade, MD⁴; Ramzi Abboud, MD⁵ ; Adrienne D. Briggs, MD⁶; Farhad Khimani, MBBS⁷ ; Dipenkumar Modi, MD⁸ ; Richard Newcomb, MD⁹ ; Elizabeth J. Shpall, MD¹⁰; Caitrin Bupp, MPH³ ; Stephen R. Spellman, MBS³; Heather E. Stefanski, MD, PhD³; Bronwen E. Shaw, MD, PhD¹¹ ; Jeffery J. Auletta, MD^{3,12} ; Steven M. Devine, MD³ ; Antonio M. Jimenez Jimenez, MD, MSc¹³ ; and Monzr M. Al Malki, MD¹⁴ 

Characteristic	PTCy URD 8/8	CNI URD 8/8	PTCy URD 7/8	CNI URD 7/8	Total
No. of patients	1,681	7,272	613	459	10,025
Patient age, years, median (range)	62.0 (18.0-82.2)	60.6 (18.0-82.7)	57.9 (18.0-78.8)	58.2 (18.1-81.4)	60.7 (18.0-82.7)
Donor age, years, median (range)	27.6 (18.0-60.9)	26.8 (18.0-66.5)	28.8 (18.0-61.2)	28.3 (18.0-61.4)	27.1 (18.0-66.5)
AML	909 (54.1)	3,937 (54.1)	330 (53.8)	243 (52.9)	5,419 (54.1)
ALL	250 (14.9)	1,209 (16.6)	128 (20.9)	93 (20.3)	1,680 (16.8)
MDS	522 (31.1)	2,126 (29.2)	155 (25.3)	123 (26.8)	2,926 (29.2)

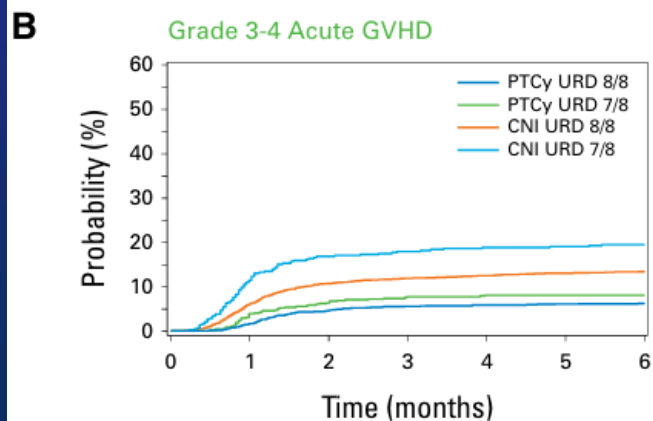


MMUD vs MUD with PTCy (CIBMTR data)



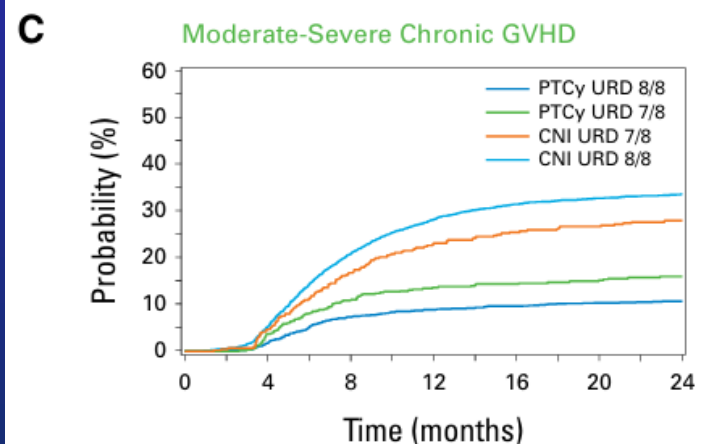
Number at risk

PTCY URD 8/8	1626	1182	1051	972
PTCY URD 7/8	596	420	365	337
CNI URD 8/8	6985	4431	3808	3490
CNI URD 7/8	446	240	199	184



Number at risk

PTCY URD 8/8	1626	1483	1393	1307
PTCY URD 7/8	596	536	497	459
CNI URD 8/8	6985	5974	5560	5207
CNI URD 7/8	446	348	318	296



Number at risk

PTCY URD 8/8	1679	1230	876	705
PTCY URD 7/8	613	424	295	237
CNI URD 8/8	7258	4220	2586	2036
CNI URD 7/8	459	254	170	138

Shaffer et al JCO 2024

Mismatch unrelated SCT with PTCy (NMDP study)

HLA match, No. (%)			
7 out of 8	26 (65)	23 (58)	49 (61)
6 out of 8	8 (20)	11 (28)	19 (24)
5 out of 8	5 (13)	2 (5)	7 (9)
4 out of 8	1 (3)	4 (10)	5 (6)

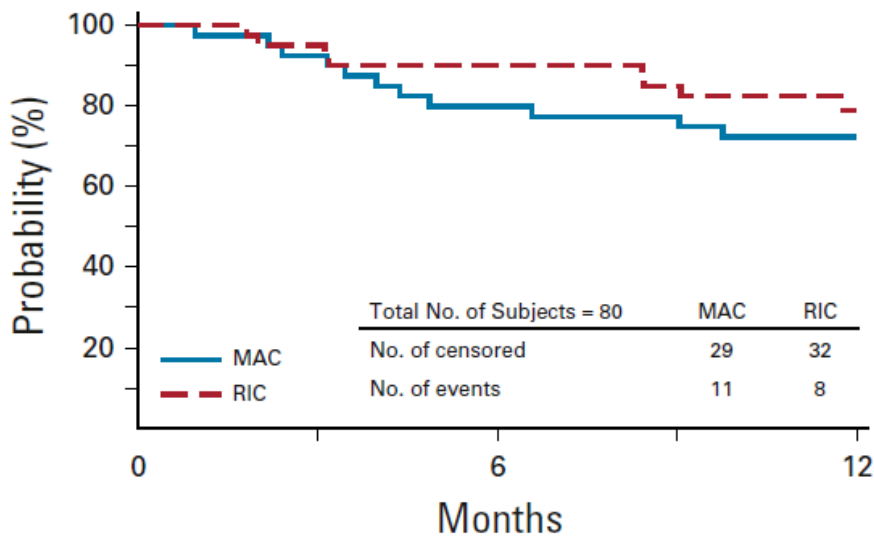
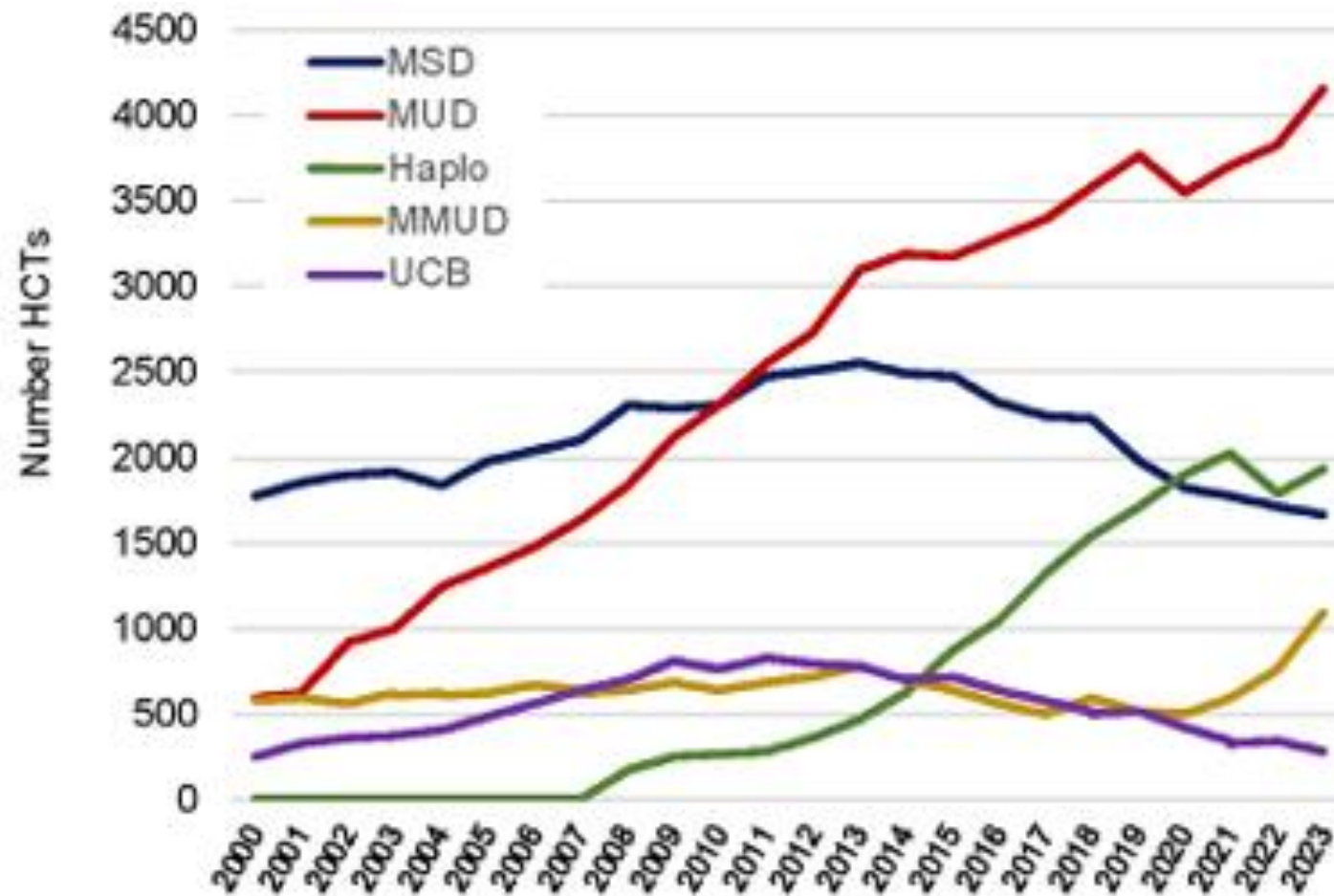


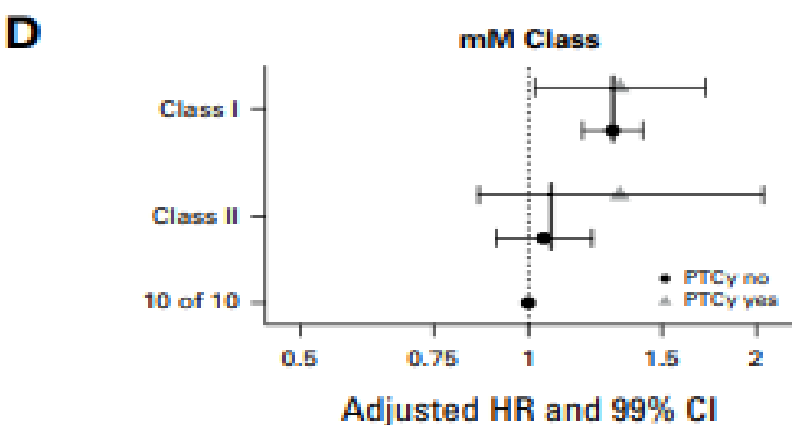
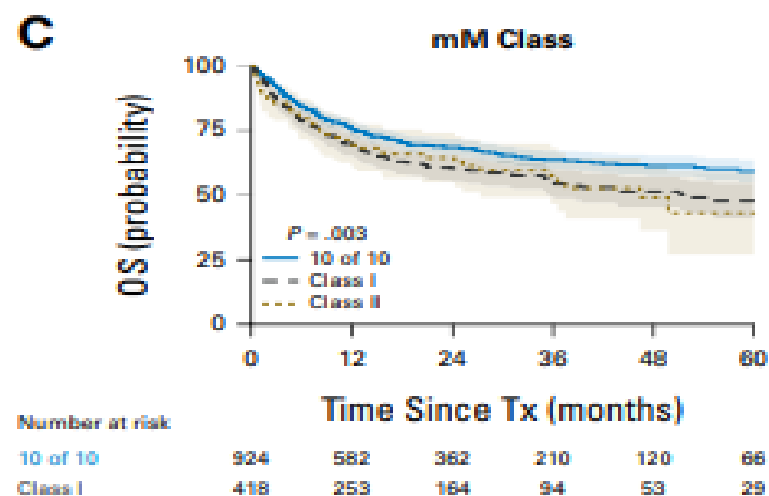
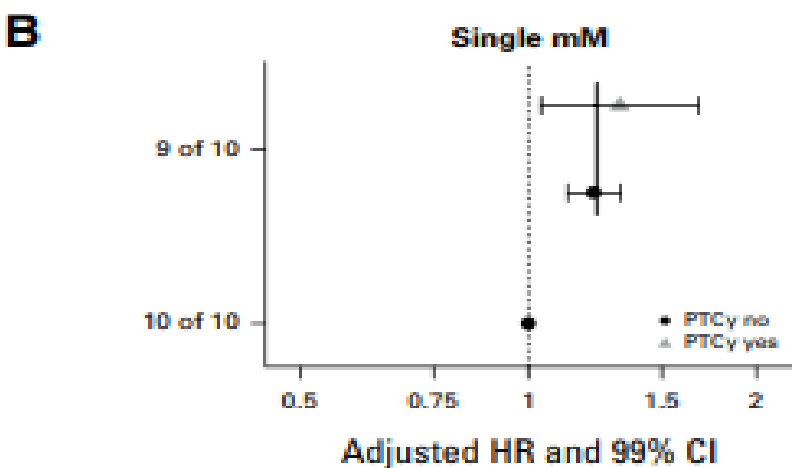
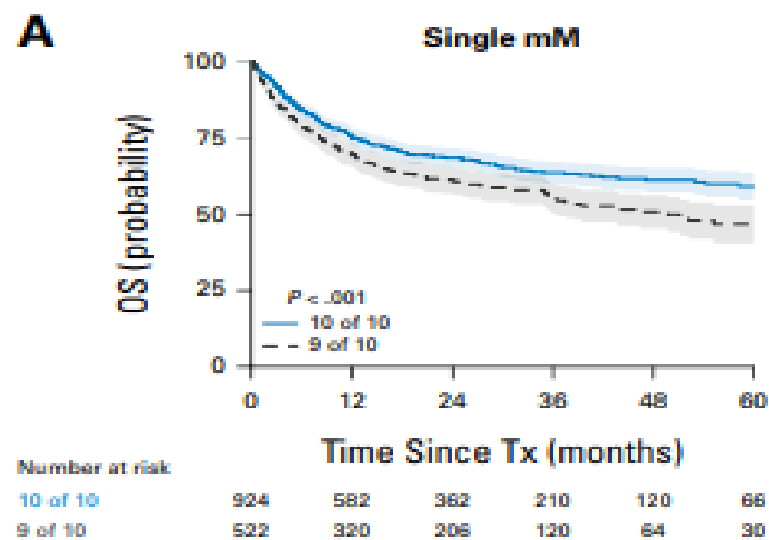
Fig 1: OS, stratified by conditioning intensity. MAC, myeloablative conditioning; OS, overall survival; RIC, reduced-intensity conditioning

No. at risk:		
MAC 40	31	17
RIC 40	36	15

CIBMTR Data



Impact of PTCy as GvHD prophylaxis on HLA-mismatch (n=1523): EBMT



ATLG/ATG vs PTCy?

Comparison of immune reconstitution between anti-T-lymphocyte globulin and posttransplant cyclophosphamide as acute graft-versus-host disease prophylaxis in allogeneic myeloablative peripheral blood stem cell transplantation



Ferrata Storti Foundation

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	N (%)	N(%)	P
Number of patients	476 (100)	123 (100)	
Leukocytes engraftment median days (range)	12 (8-36)	16 (12-27)	<0.001
Platelet engraftment median days (range)	15 (8-99)	21 (9-99)	0.024
CMV reactivation [15 in ATG 54 in PTCY missing]	214 (46)	60 (50)	NS
EBV reactivation [34 in ATG missing, 4 in PTCY missing]	131 (33)	19 (16)	<0.001
Overall incidence of infection by day 100	344 (75)	109 (91)	<0.001
NRM at 3 years	16%	30%	0.006
Relapse incidence	34%	29%	NS
DFS at 3 years	50%	42%	NS
OS at 3 years	65%	58%	NS
Moderate/severe cGVHD Relapse free survival	40%	27%	NS

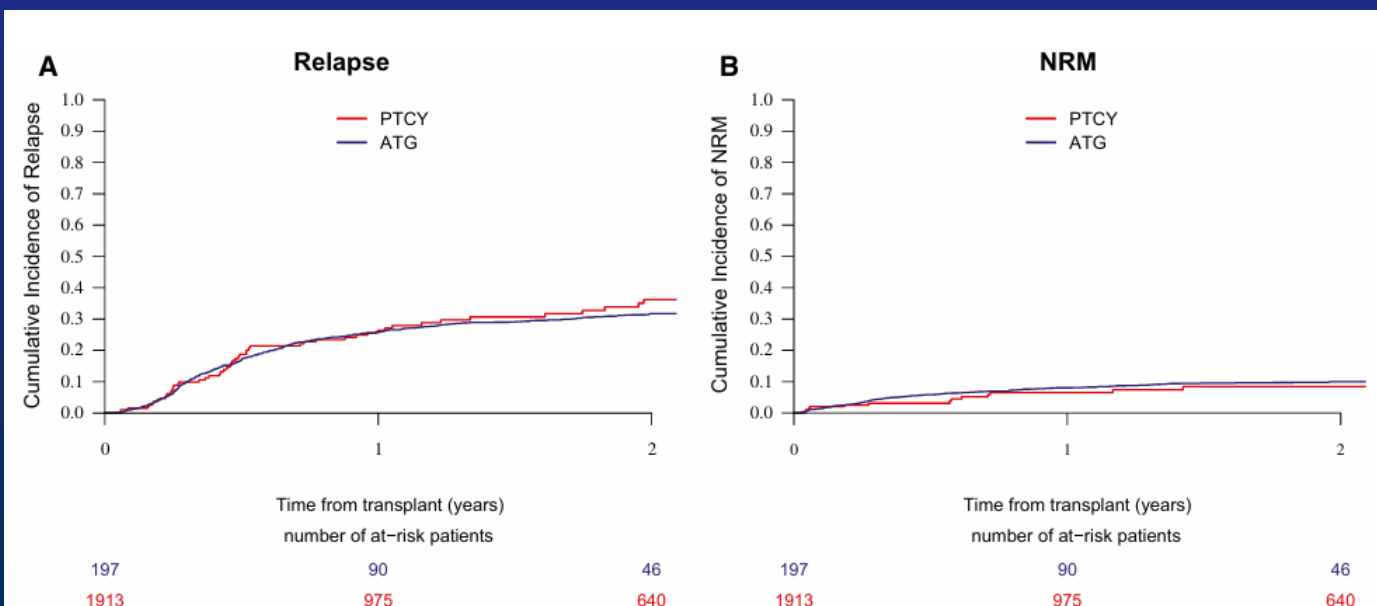
Legend: NS= statistically non-significant, NRM= Non relapse Mortality, OS= Overall survival, DFS= disease free survival, cGVHD= Chronic graft versus host disease

CD8, NK, NKT, gamma/delta T cells faster after ATG and CD4 after PTCy
Moderate /severe cGvHD after ATG vs PTCy: 38% vs 44%, p=0.005

ATG vs PTCY in AML and HLA-ident Sibling HSCT (EBMT)

TABLE 1. Patient, Disease, and Transplantation Characteristics

Characteristic	ATG (n = 1913)	PTCY (n = 197)	<i>P</i>
Age at allo-HCT, y, median (range)	54 (18-72)	47 (18-74)	<.01
Sex			.55
Men	1012 (53)	88 (55)	
Women	893 (47)	88 (45)	
Female donor into male recipient	456 (24)	51 (26)	.55
Secondary AML	318 (17)	31 (16)	.75
Cytogenetic risk			.51
Good	67 (3)	8 (4)	
Intermediate	869 (45)	87 (44)	
Poor	347 (19)	29 (15)	
NA/Failed	630 (33)	73 (37)	



ATG vs PTCY in AML and HLA-ident Sibling HSCT (EBMT)

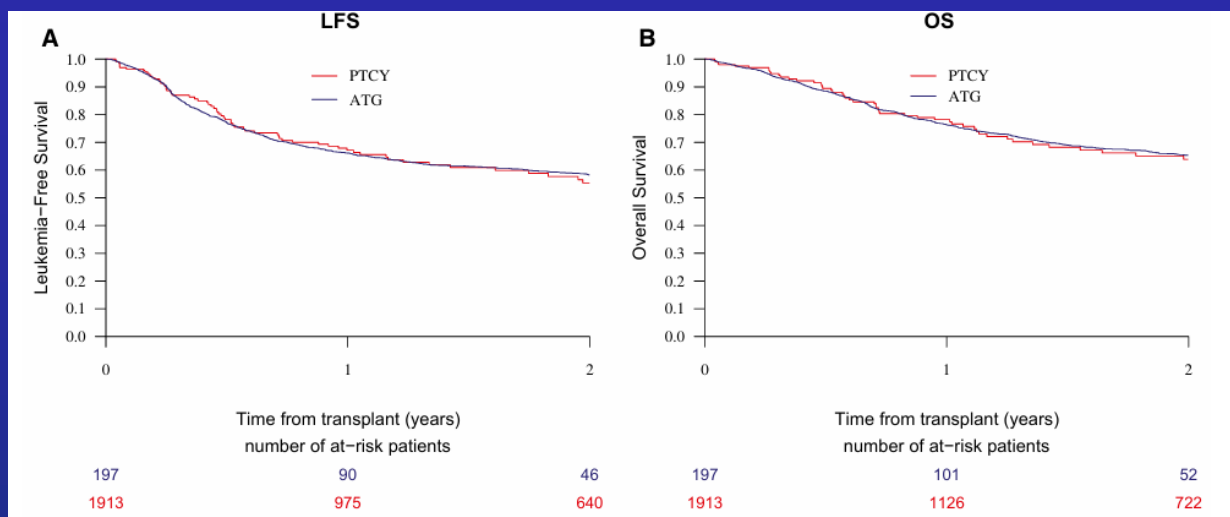
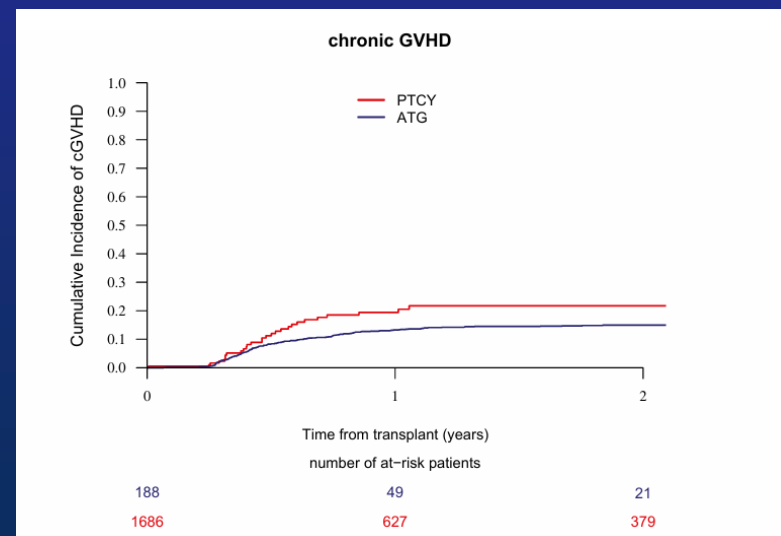


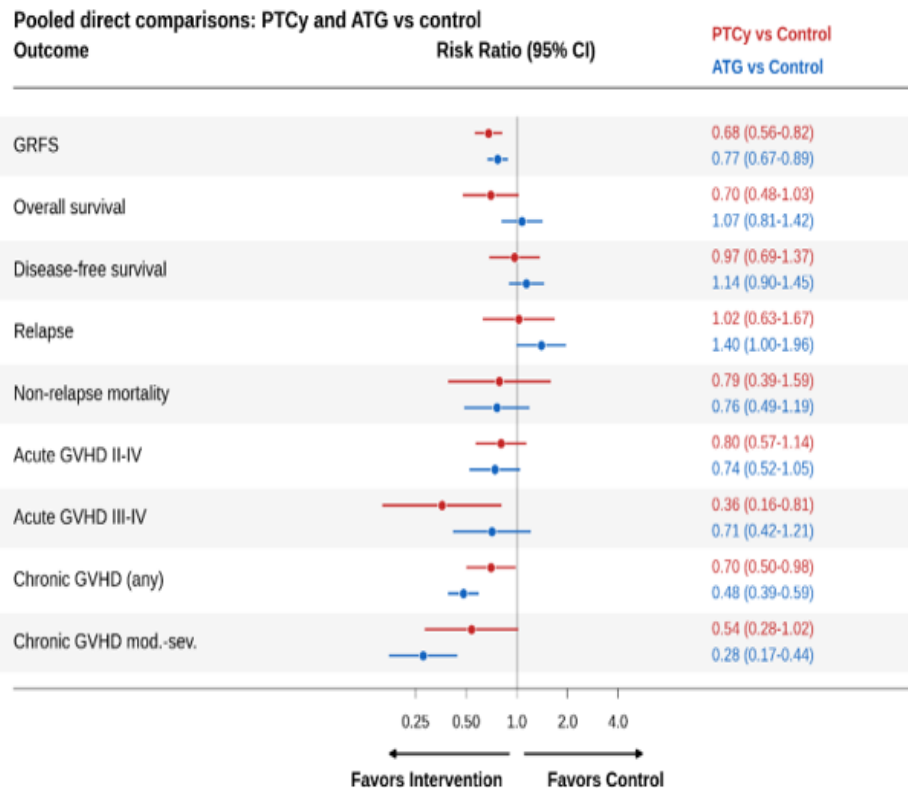
TABLE 3. Multivariate Analysis

ATG vs PTCY	HR (95% CI)	P
LFS	1.00 (0.77-1.31)	.99
OS	0.97 (0.72-1.32)	.86
GRFS	0.85 (0.67-1.03)	.16
RI	0.97 (0.72-1.31)	.85
NRM	1.15 (0.63-2.11)	.65
Grade II-IV acute GVHD	0.96 (0.66-1.41)	.84
Grade III/IV acute GVHD	0.82 (0.43-1.58)	.56
Chronic GVHD, all grades	0.71 (0.52-0.97)	<.04
Extensive chronic GVHD	0.60 (0.38-0.93)	<.03

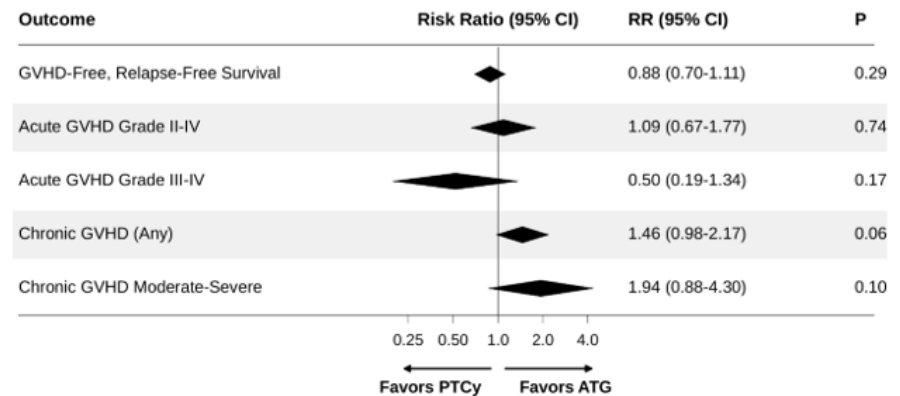


A network meta-analysis of randomized trials to determine optimal GVHD prophylaxis in matched sibling donor transplantation

Gonzalo Bentolila¹, Nihar Desai², Shernan Holtan³, Francesca Bonifazi⁴, Annoek E C Broers⁵, Jonas Mattsson², Juliana Martinez Rolon⁶, Thomas Schroeder⁷, Nicolaus Kröger⁷, Nico Gagelmann⁸



Indirect Comparison: GVHD Outcomes



RESEARCH

Open Access



Post-transplant cyclophosphamide versus antithymocyte globulin in patients with acute myeloid leukemia in first complete remission undergoing allogeneic stem cell transplantation from 10/10 HLA-matched unrelated donors

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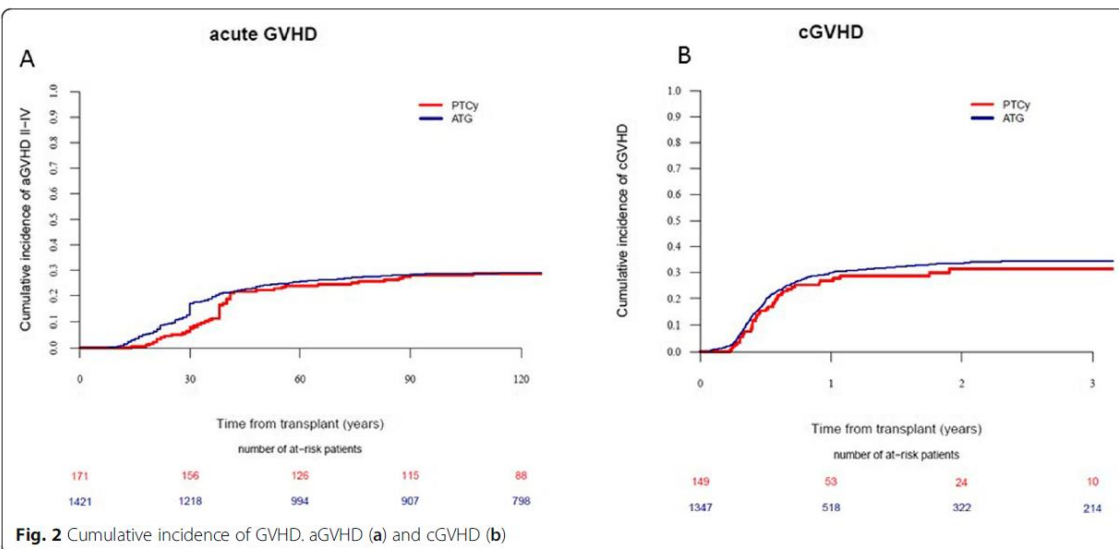
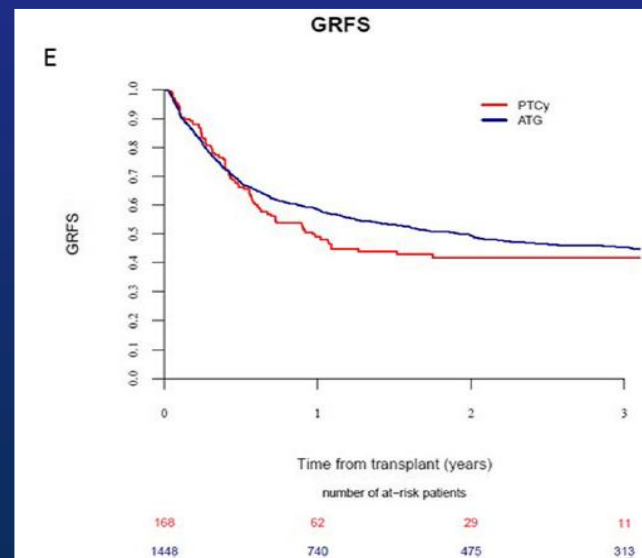
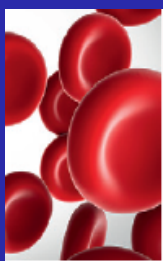


Fig. 2 Cumulative incidence of GVHD. aGVHD (a) and cGVHD (b)

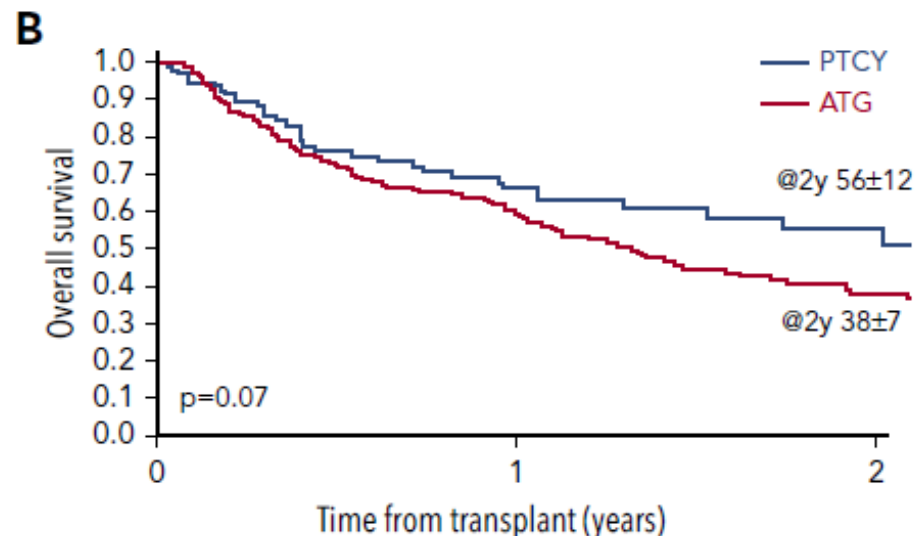
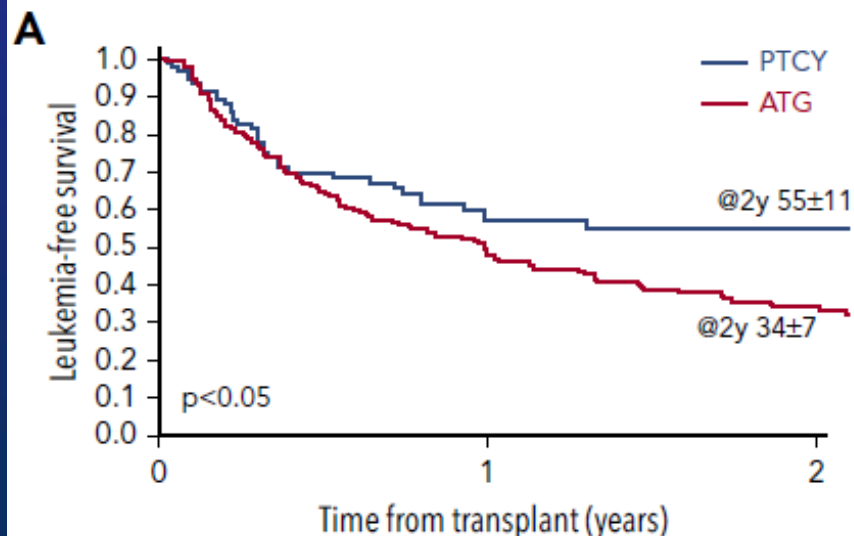




TRANSPLANTATION

Posttransplant cyclophosphamide vs antithymocyte globulin in HLA-mismatched unrelated donor transplantation

Giorgia Battipaglia,^{1,2} Myriam Labopin,^{1,3,4} Nicolaus Kröger,⁵ Antonin Vitek,⁶ Boris Afanasyev,⁷ Inken Hilgendorf,⁸ Johannes Schetelig,⁹ Arnold Ganser,¹⁰ Didier Blaise,¹¹ Maija Itälä-Remes,¹² Jakob R. Passweg,¹³ Francesca Bonifazi,¹⁴ Jurgen Finke,¹⁵ Annalisa Ruggeri,¹⁶ Arnon Nagler,^{3,17} and Mohamad Mohty^{1,3,4}



GVHD PROPHYLAXIS INCLUDING ATG REMAINS STANDARD OF CARE FOR HLA-COMPATIBLE UNRELATED DONOR HEMATOPOIETIC CELL TRANSPLANTATION: RESULTS FROM A LARGE RANDOMIZED CONTROLLED TRIAL COMPARING ATG AND PTCY

Johannes Schetelig

Author(s): Matthias Stelljes, Désirée Kunadt, Thomas Schröder, Lutz Peter Müller, Friedrich Stölzel, Gesine Bug, Edgar Jost, Anke Morgner, Johannes Lakner, Kerstin Schäfer-Eckart, Lorenz Thurner, Christoph Schmid, Wolfgang Bethge, Martin Kaufmann, Stefan A. Klein, Andreas Burchert, Friederike Wortmann, Ralf-Georg Meyer, Inken Hilgendorf, Udo Holtick, Guido Kobbe, Jochen J. Frietsch, Eva Wagner-Drouet, Mark Ringhoffer, Matthias Floeth, Jan Moritz Middeke, Judith Schaffrath, Henning Baldauf, Carina Rave, Ruben Real, Cathleen Petzold, Sarah Trost, Alexander H. Schmidt, Vinzenz Lange, Hans C. Reinhardt, Christian Reicherts, Georg Lenz, Martin Bornhäuser, Johannes Schetelig

Non-inferiority for PTCY

640 patients were randomized between 3/2022 and 12/2024, stratified for age, disease risk and HLA-compatibility, 383 to PTCy-100 and 257 to ATG-30.

median age was 63 years (range, 19-78)

disease risk index was high or very high for 363 patients (57%)

Majority not in (molecular) CR!

10% MMUD

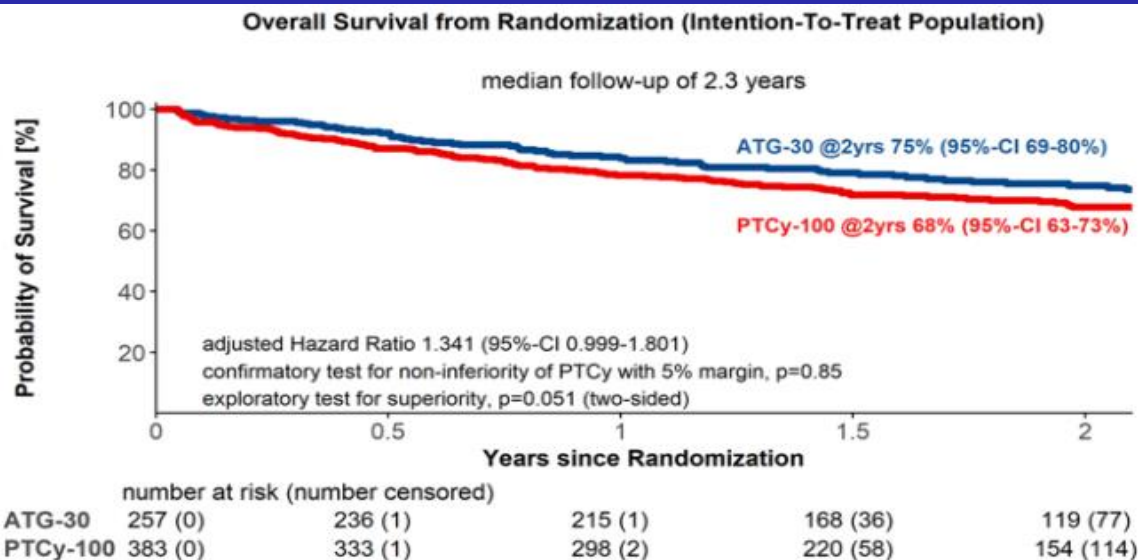


Figure 1.

GRFS at 2 years after HCT was 48% with PTCy-100 versus 40% with ATG-30 (adj. HR 0.85, $p=0.16$)
CI of relapse at 2 years after HCT were **26% and 31%** (adj. HR 0.86, $p=0.32$)
 NRM was higher with PTCy-100 than with ATG-30 (**2-year NRM 13% versus 7%**, adj. HR 1.86, $p=0.02$),
specifically due to infections w/o concomitant severe acute or cGVHD in the **PTCy-100** arm.

Confirmatory testing

- Non-inferior survival with a margin of 5% for PTCy-100 can **not** be shown compared to ATLG-30

Explorative testing

PTCy-100
2yr OS 68%
2yr NRM 13%

ATLG-30
2yr OS 75%
2yr NRM 7%

- PTCy-100: lower incidences of acute and chronic GVHD, but longer aplasia, longer in hospital stay, more infections, higher infectious mortality, higher NRM

Summary

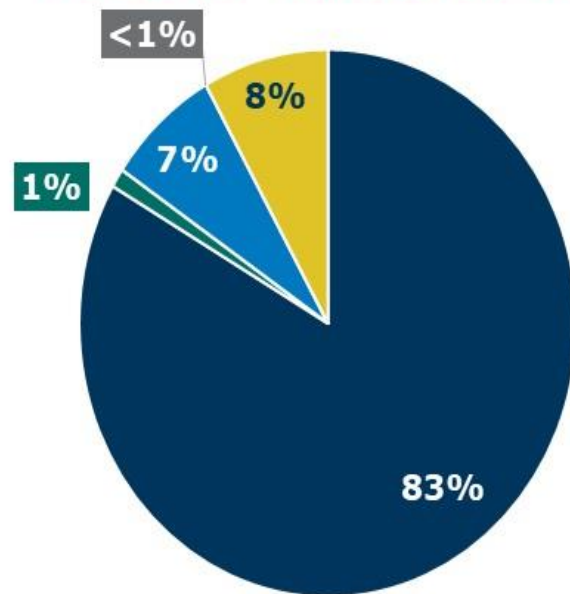
1. Post-transplant Cyclophosphamide can be recommended for all donor sources to prevent acute and chronic GvHD
2. However it is not clear whether it should be preferred to ATG/ATLG as GvHD prophylaxis

Current clinical research is focussed on:

- a) optimal dosing of PTCy to reduce toxicity and prevent GvHD
- b) find optimal combination partner for different donor source (including ATG/ATLG plus PTCy combination)

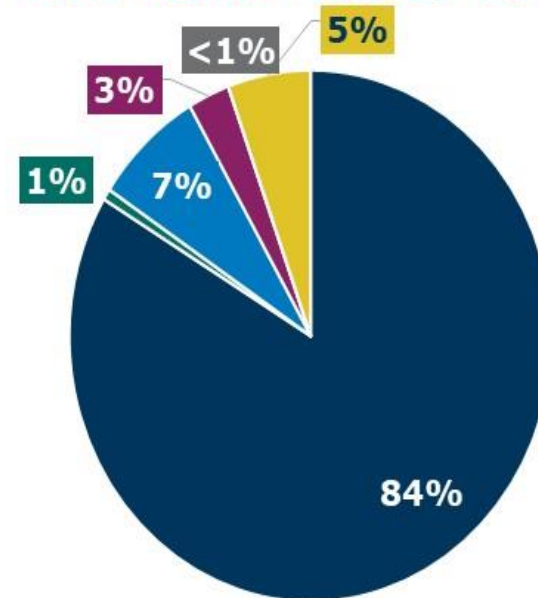
PTCy-based GVHD prophylaxis - PTCy partners, Matched Donors, 2024, adults

Matched related donor



n = 626

Matched unrelated donor



n = 2829

■ CNI + MMF ■ CNI + MTX ■ Siro ■ Abatacept ■ PTCy alone ■ PTCy + other(s)

‘PTCy – for ALL donors?’ w. Leo Luznik

In this episode Prof. Leo Luznik will describe how post-transplant cyclophosphamide as effective GvHD prophylaxis was detected and used after haploidentical allogeneic transplantation and its current and future role in HLA identical sibling, as well as in matched and mismatched unrelated stem cell transplantation.



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