XXI Congreso Chileno de Hematología y
XI Congreso de Medicina Transfusional

Sociedad Chilena de Hematología

Indicaciones de TPH, acondicionamiento, donante

Mi Kwon

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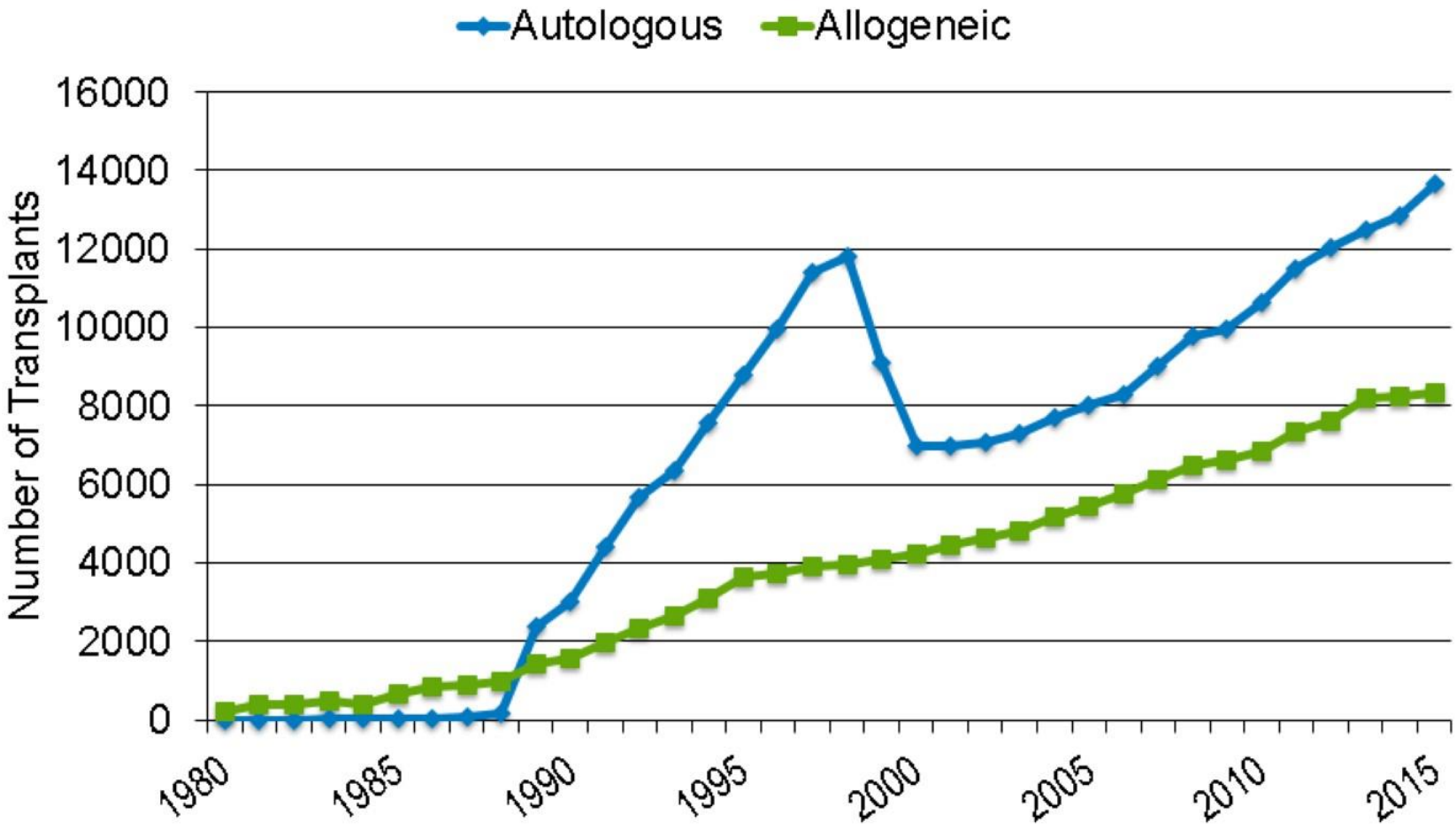
Agosto 2018

SaludMadrid
Hospital General Universitario Gregorio Marañón
Comunidad de Madrid
IIS G-M
Instituto de Investigación Sanitaria Gregorio Marañon
GETH
GRUPO ESPAÑOL DE TRASPLANTE HEMATOPOYÉTICO Y TERAPIA CELULAR

Introducción

- El TPH alogénico ofrece un potencial curativo para múltiples trastornos hematológicos benignos y malignos
- Su uso se ha extendido a lo largo de los años, debido en parte a la introducción de acondicionamientos de intensidad reducida y al avance en el campo del donante alternativo
- La posibilidad de recibir un tipo específico de TPH depende de las políticas del centro trasplantador y su experiencia

Annual Number of HCT Recipients in the US by Transplant Type



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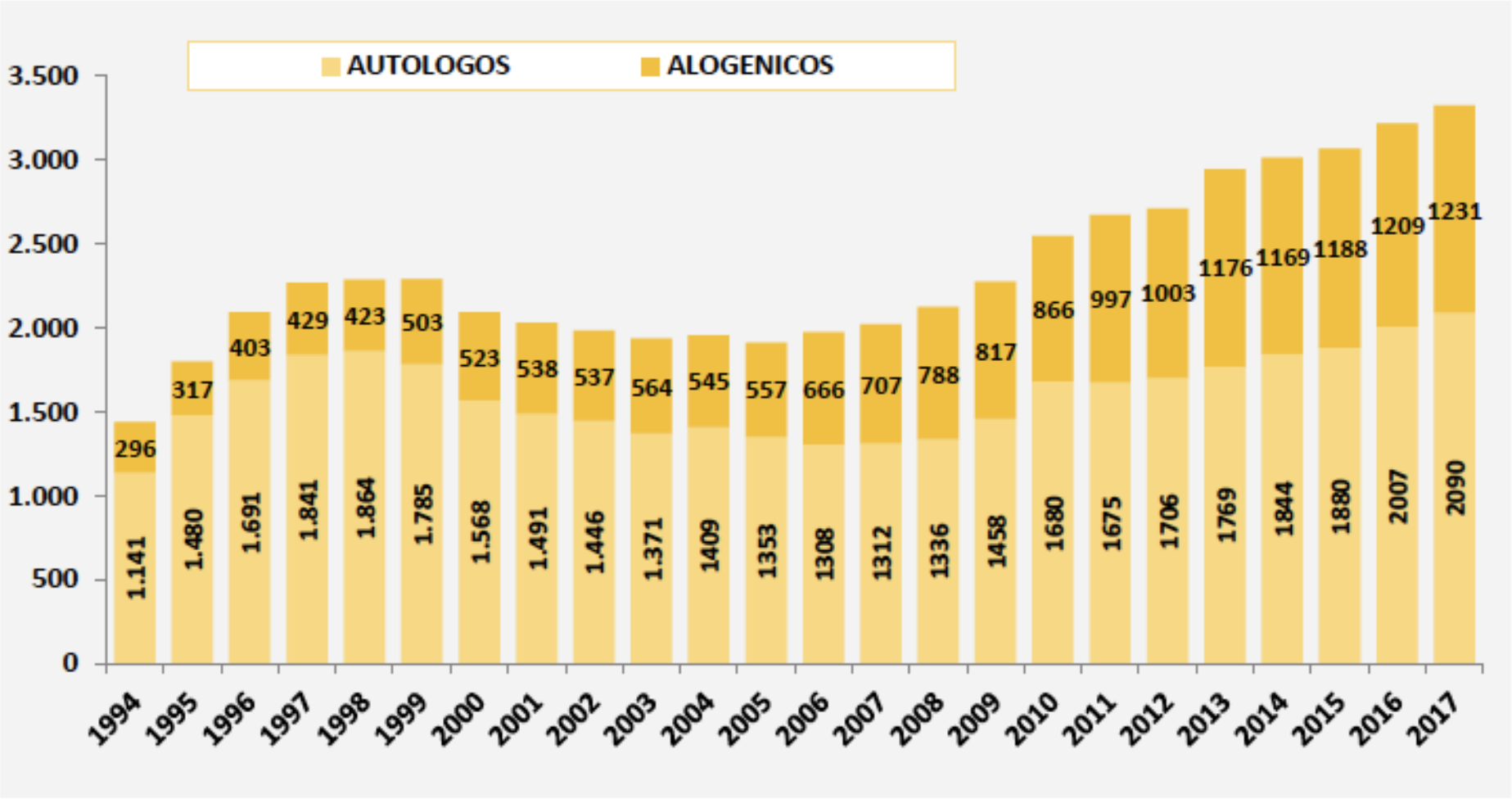
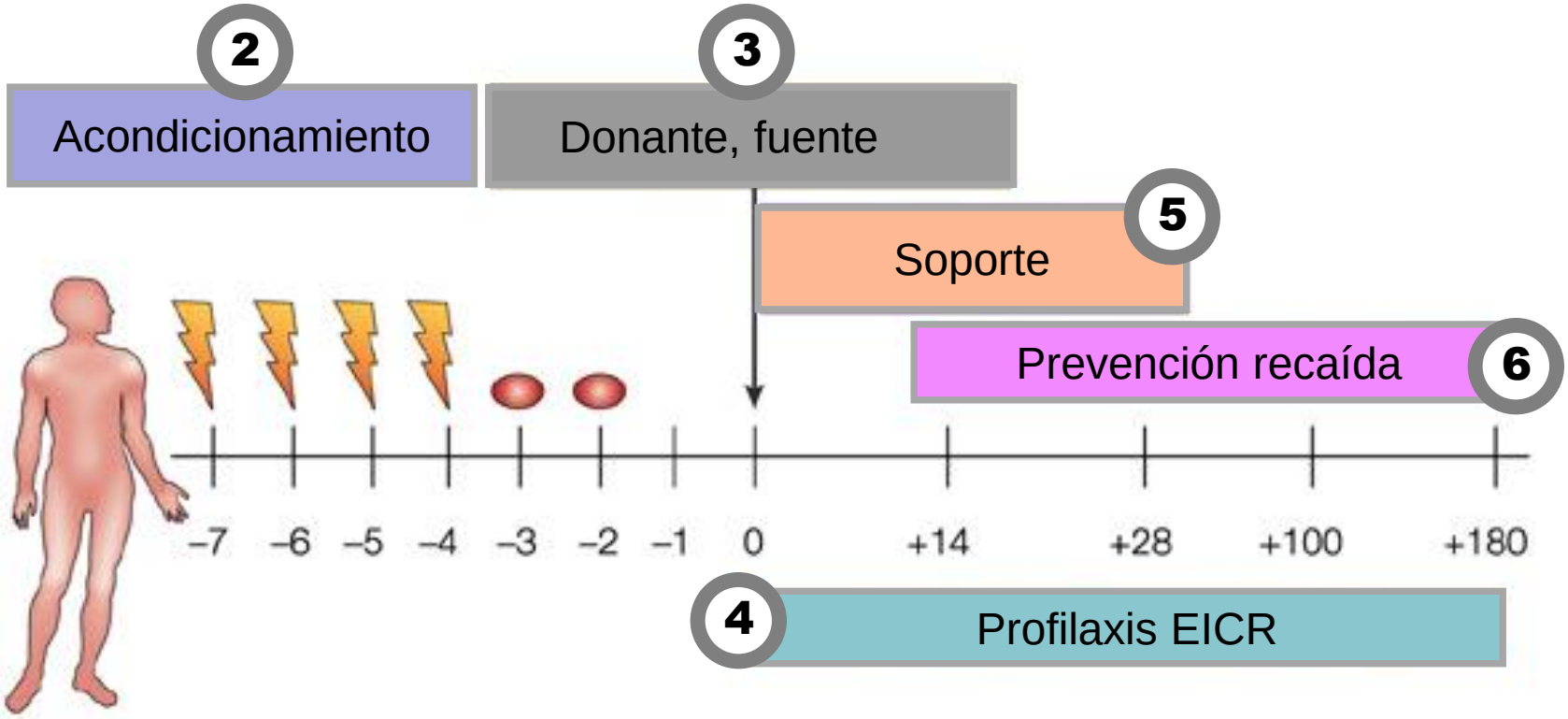
Organización Nacional Trasplantes

Trasplantes de progenitores hematopoyéticos Tipos. España. 1994-2017



El TPH alogénico



Adaptado de M Bleakley, S Riddell. Nature Reviews Cancer 4, 2004

SPECIAL REPORT

Bone Marrow Transplantation (2015) **50,** 1037–1056

Indications for allo- and auto-SCT for haematological diseases, solid tumours and immune disorders: current practice in Europe, 2015

A Sureda[1], P Bader[2], S Cesaro[3], P Dreger[4], RF Duarte[1], C Dufour[5], JHF Falkenburg[6], D Farge-Bancel[7], A Gennery[8], N Kröger[9], F Lanza[10], JC Marsh[11], A Nagler[12], C Peters[13], A Velardi[14], M Mohty[15,17] and A Madrigal[16,17] for the European Society for Blood and Marrow Transplantation

American Society of Blood and Marrow Transplantation Guidelines for Training in Hematopoietic Progenitor Cell Transplantation

Shakila Khan,[1] Mark B. Juckett,[2] Krishna V. Komanduri,[3] Amrita Krishnan,[4] Linda J. Burns,[5] for the American Society of Blood and Marrow Transplantation Committee on Education

Biol Blood Marrow Transplant 18:1322-1328, 2012

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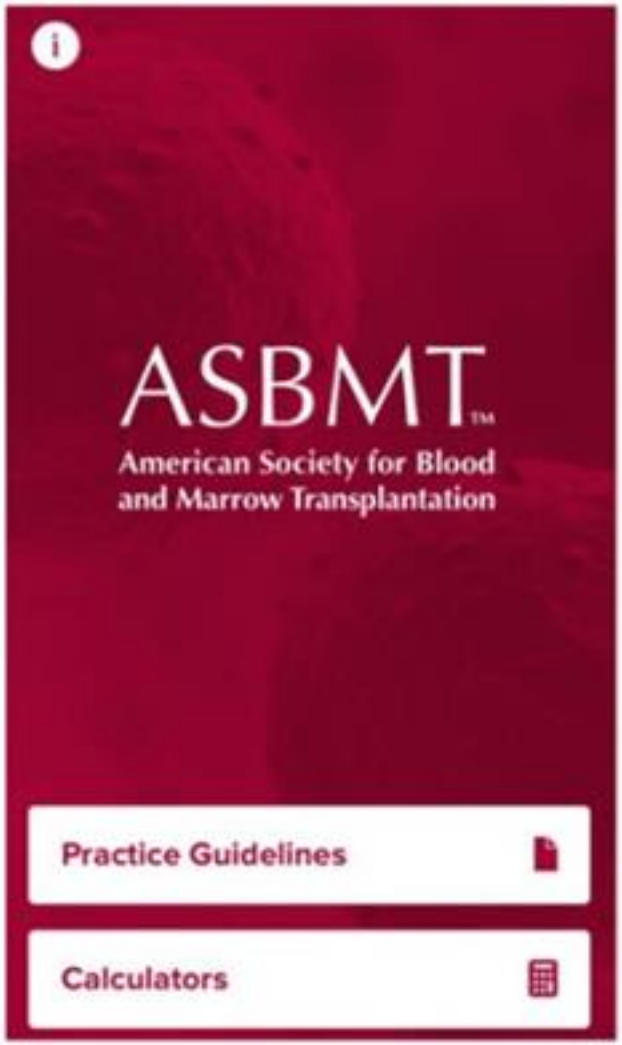
GETH

GRUPO ESPAÑOL DE TRASPLANTE HEMATOPOYÉTICO Y TERAPIA CELULAR

DOCUMENTO GETH INDICACIONES de TPH EN ADULTOS



Introducing the new ASBMT

Practice Guidelines App

With immediate access to:

- Updated practice guidelines
- Evidence-based Reviews
- Clinical Calculators
- Position Statements from the ASBMT Committee on Practice Guidelines.

The ASBMT Practice Guidelines mobile app is now available for download on IOS and Android platforms.

Indications for HCT in Pediatric Patients (Generally Age < 18 years) - Leukemia/MDS

INDICATION AND DISEASE STATUS	**Acute myeloid leukemia**

INDICATION AND DISEASE STATUS	CR1, low risk
ALLOGENEIC HCT	N
AUTOLOGOUS HCT	N

INDICATION AND DISEASE STATUS	CR1, intermediate risk
ALLOGENEIC HCT	C
AUTOLOGOUS HCT	N

INDICATION AND DISEASE STATUS	CR1, high risk
ALLOGENEIC HCT	S
AUTOLOGOUS HCT	N

Back Indications for HCT in P...

Indications for HCT in Pediatric Patients (Generally Age < 18 years) - Lymphoma

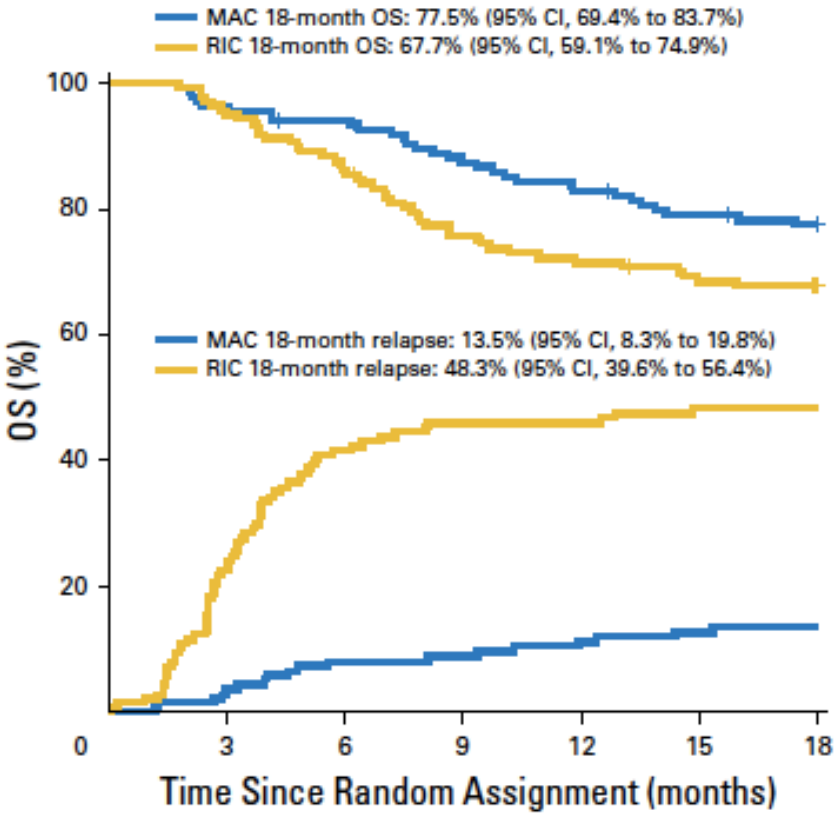
INDICATION AND DISEASE STATUS	**T cell non-Hodgkin lymphoma**

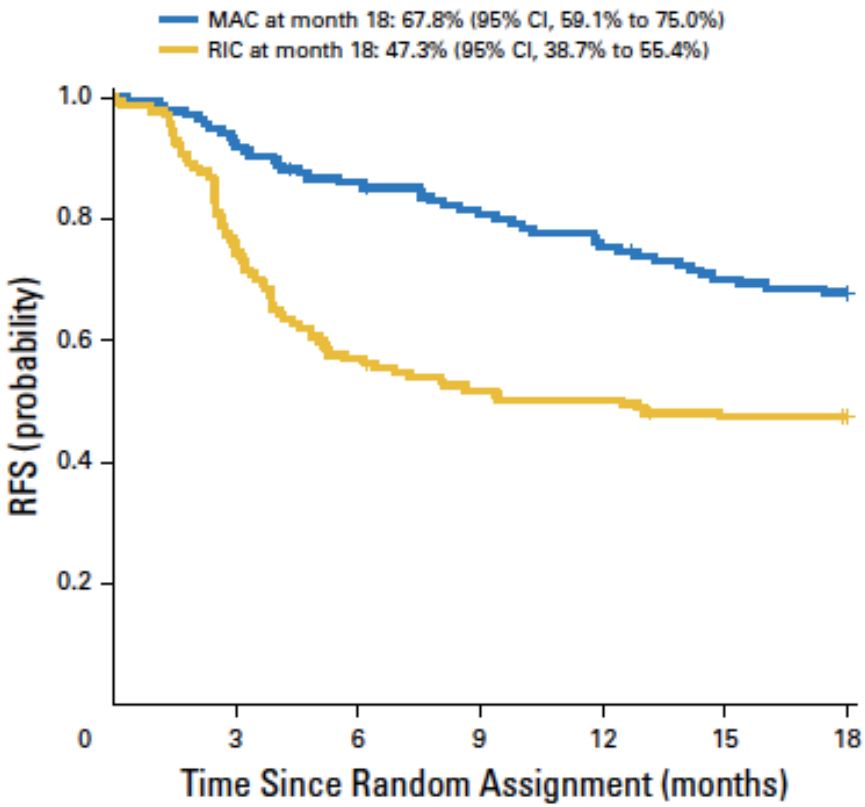
INDICATION AND DISEASE STATUS	CR1, standard risk
ALLOGENEIC HCT	N
AUTOLOGOUS HCT	N

INDICATION AND DISEASE STATUS	CR1, high risk
ALLOGENEIC HCT	S
AUTOLOGOUS HCT	N

INDICATION AND DISEASE STATUS	CR2
ALLOGENEIC HCT	S
AUTOLOGOUS HCT	N

LMA: MA vs AIR



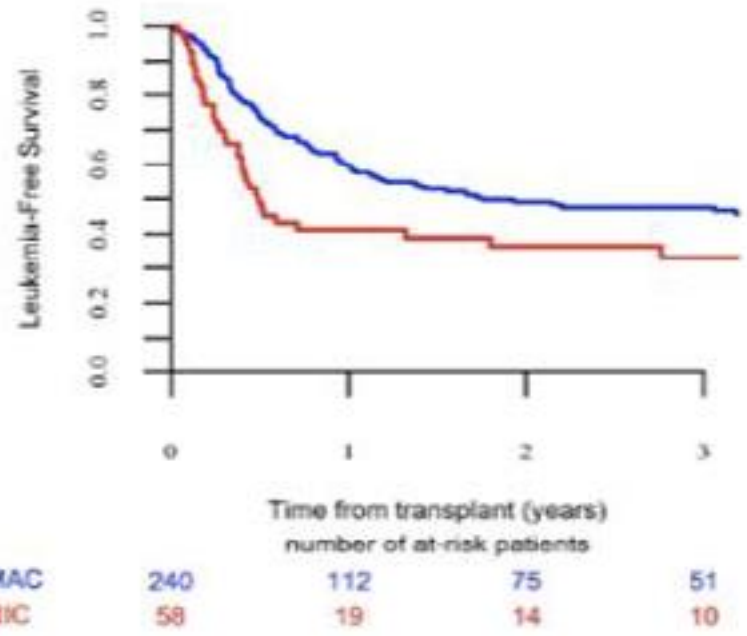


Scott *et al.* JCO 2017

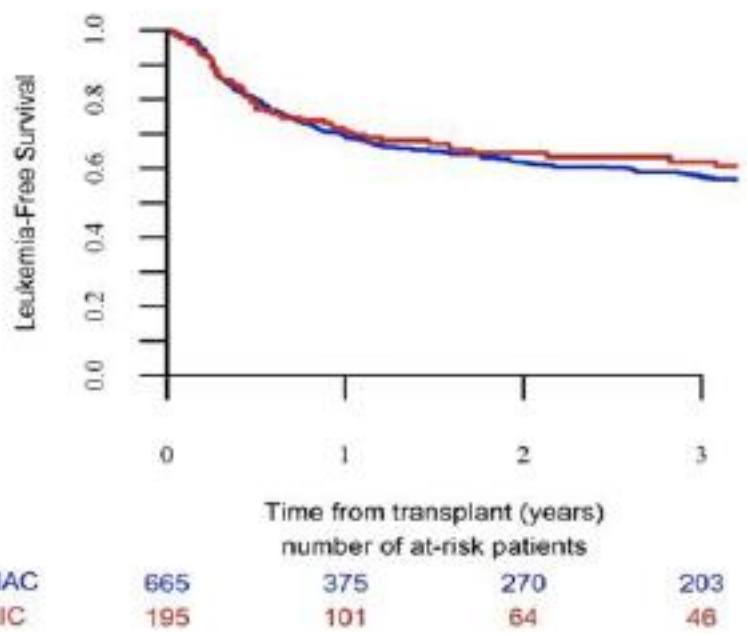
Measurable residual disease, conditioning regimen intensity and age predict outcome of allogeneic HSCT for AML in first remission: a registry analysis of 2292 patients by the Acute Leukemia Working Party EBMT

Pacientes < 50 años

LFS EMR pos



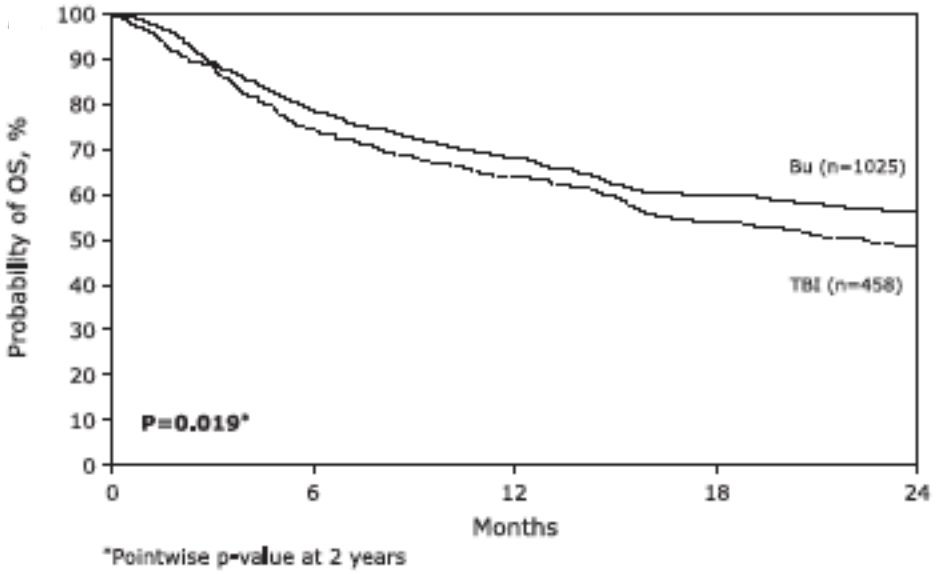
LFS EMR neg

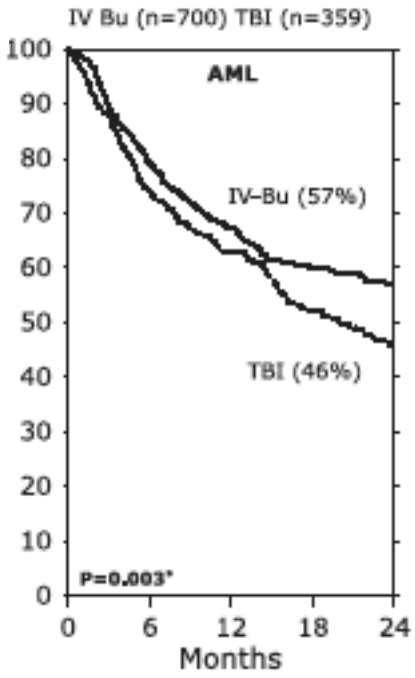


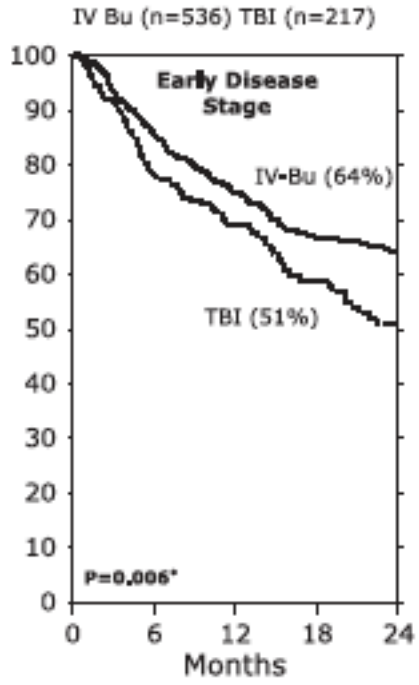
Gilleece *et al.* Am J Hematol 2018

Prospective cohort study comparing intravenous busulfan to total body irradiation in hematopoietic cell transplantation

Christopher Bredeson,[1] Jennifer LeRademacher,[2] Kazunobu Kato,[3] John F. DiPersio,[4] Edward Agura,[5] Steven M. Devine,[6] Frederick R. Appelbaum,[7] Marcie R. Tomblyn,[8] Ginna G. Laport,[9] Xiaochun Zhu,[2] Philip L. McCarthy,[10] Vincent T. Ho,[11] Kenneth R. Cooke,[12] Elizabeth Armstrong,[3] Angela Smith,[3] J. Douglas Rizzo,[2] Jeanne M. Burkart,[2] and Marcelo C. Pasquini[2]







Limitaciones de TBI:

- Edad y comorbilidades
- RT previa
- Complejidad logística
- Mayor EICH aguda por daño de órgano directo

Blood 2013;122:3821

BUCY vs BUFLU

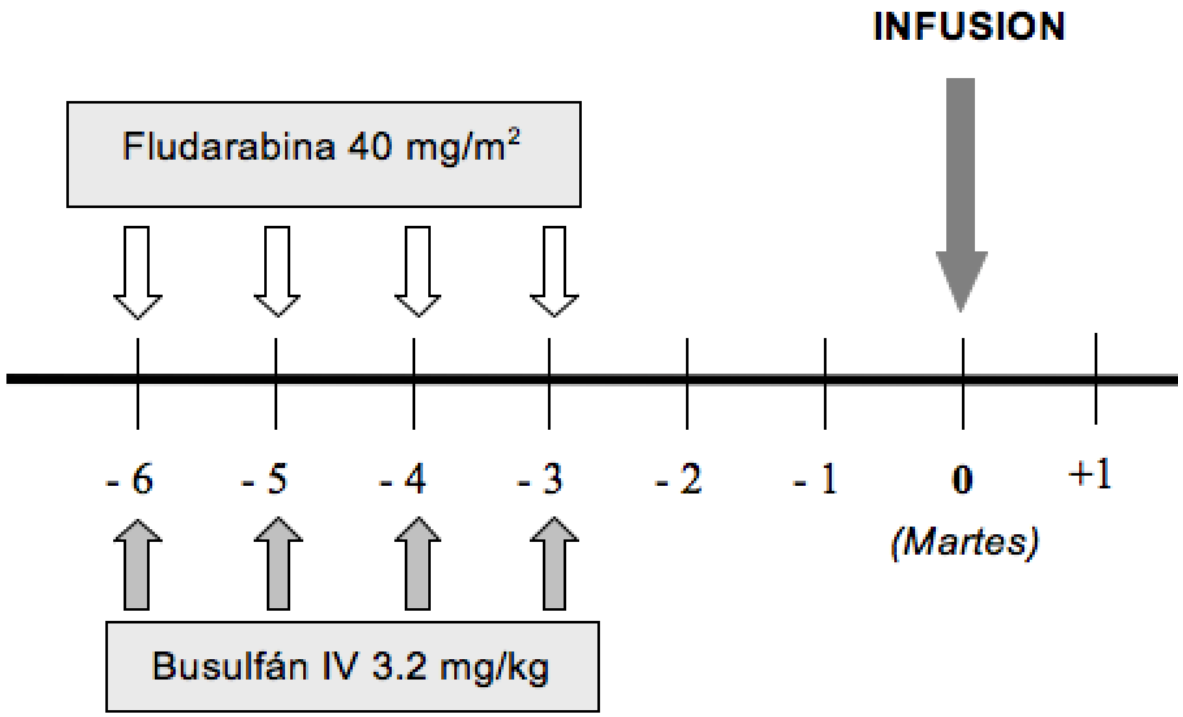
Original Article

Busulfan plus fludarabine compared with busulfan plus cyclophosphamide as a conditioning regimen prior to hematopoietic stem cell transplantation in patients with hematologic neoplasms: a meta-analysis

- No diferencias estadísticamente significativas en SG, SLE y MRT
- No diferencias estadísticamente significativas en EICH
- Mayor toxicidad hepática (RR 1.90) con BUCY

Lei *et al*, Int J Clin Exp Med 2015

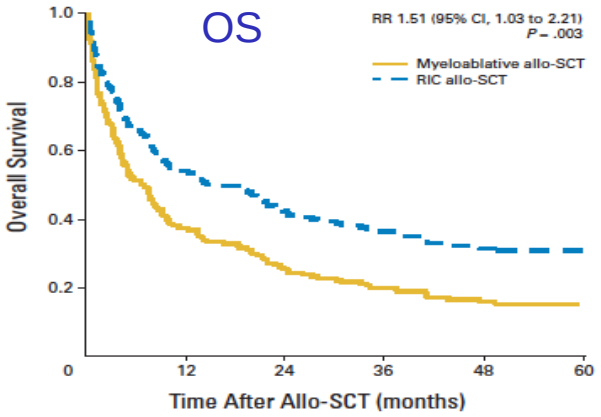
Acondicionamiento Mieloablativo Hospital Gregorio Marañón

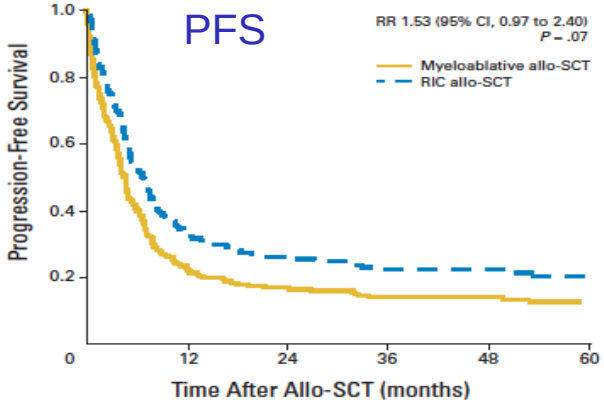


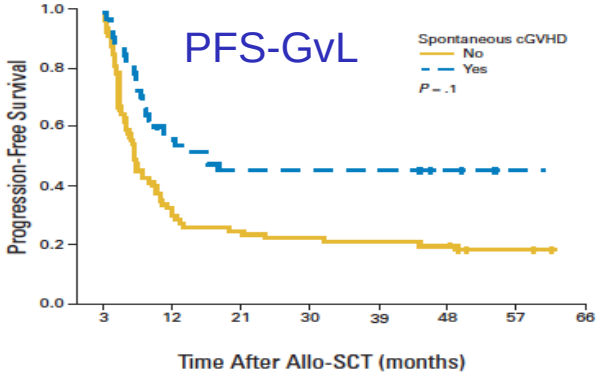
Linfoma Hodgkin: MA vs AIR

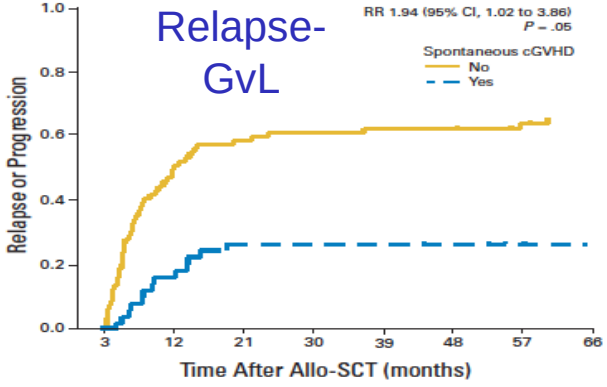
Reduced-Intensity Conditioning Compared With Conventional Allogeneic Stem-Cell Transplantation in Relapsed or Refractory Hodgkin's Lymphoma: An Analysis From the Lymphoma Working Party of the European Group for Blood and Marrow Transplantation

Anna Sureda, Stephen Robinson, Carmen Canals, Angelo M. Carella, Marc A. Boogaerts, Dolores Caballero, Ann E. Hunter, Lothar Kanz, Shimon Slavin, Jan J. Cornelissen, Martin Gramatzki, Dietger Niederwieser, Nigel H. Russell, and Norbert Schmitz



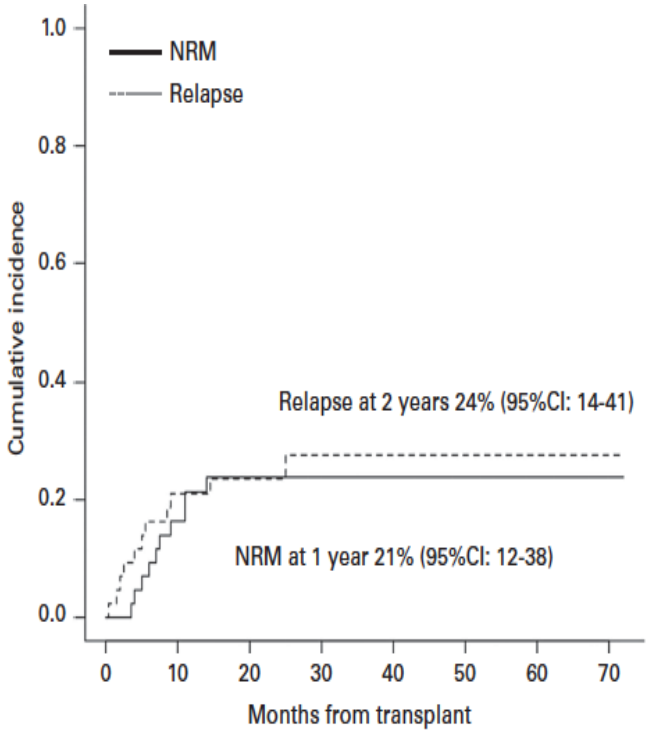


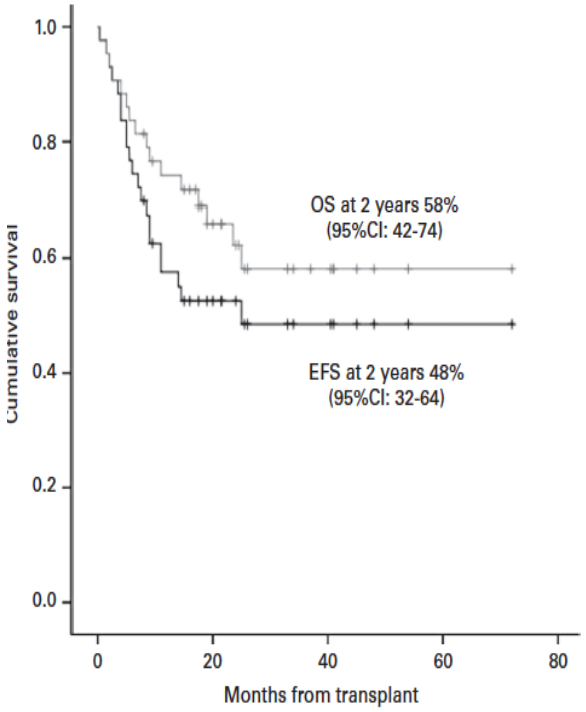




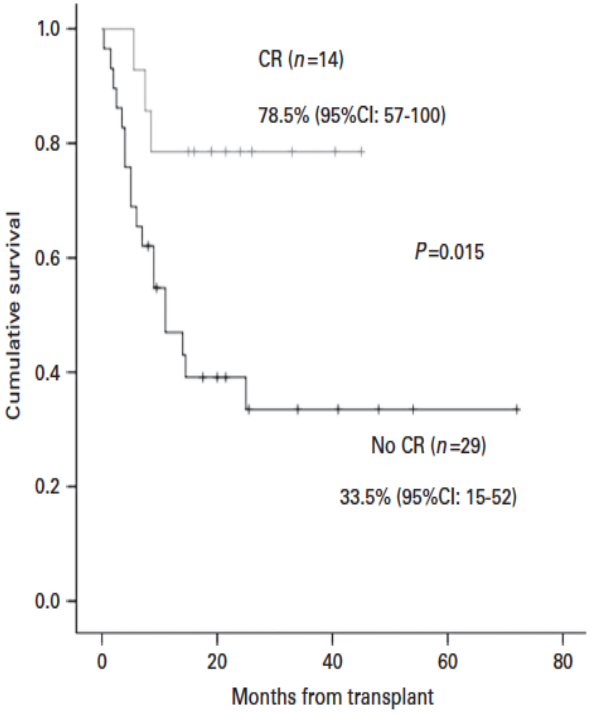
Sureda A, *et al.* Journal Clin Oncol 2008

Busulfan-based RIC for Haplo-SCT in r/r Hodgkin lymphoma: Spanish multicenter experience



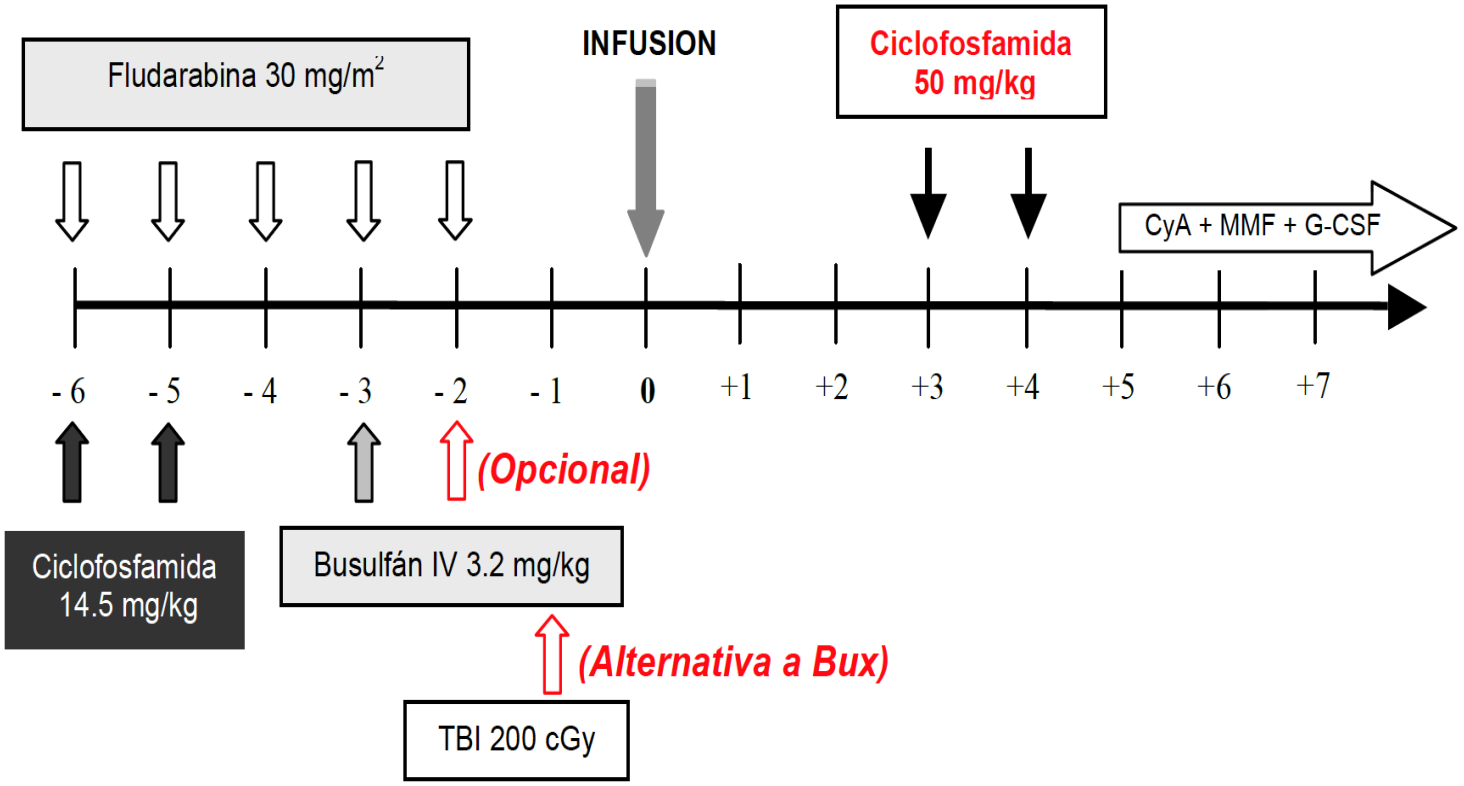


2-year PFS according to CR status



Gayoso J, *et al*. Bone Marrow Transpl 2016

Acondicionamiento Intensidad Reducida Haploidéntico con CY-PT Hospital Gregorio Marañón



Evaluación de la comorbilidad pre-TPH

VOLUME 32 · NUMBER 29 · OCTOBER 10 2014

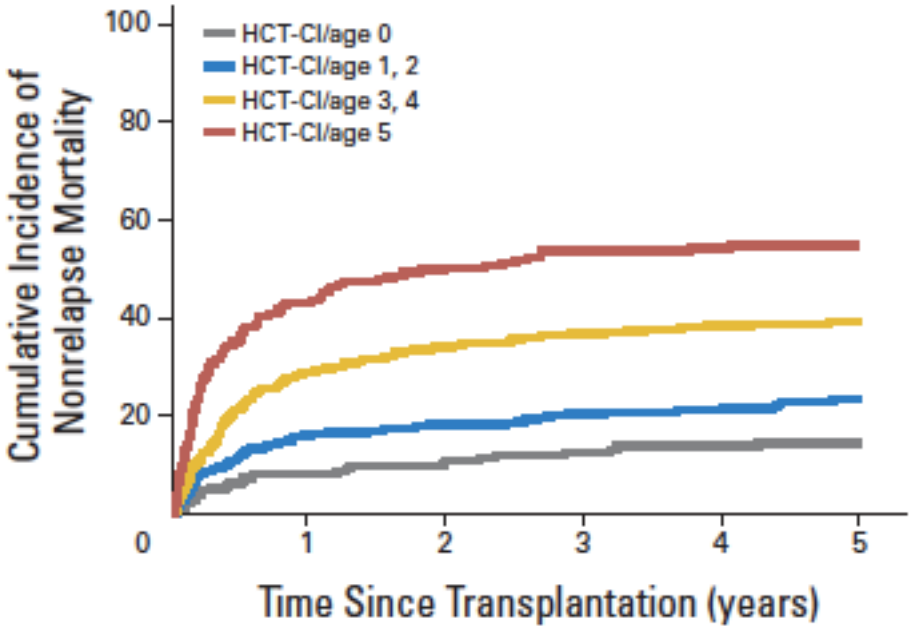
JOURNAL OF CLINICAL ONCOLOGY

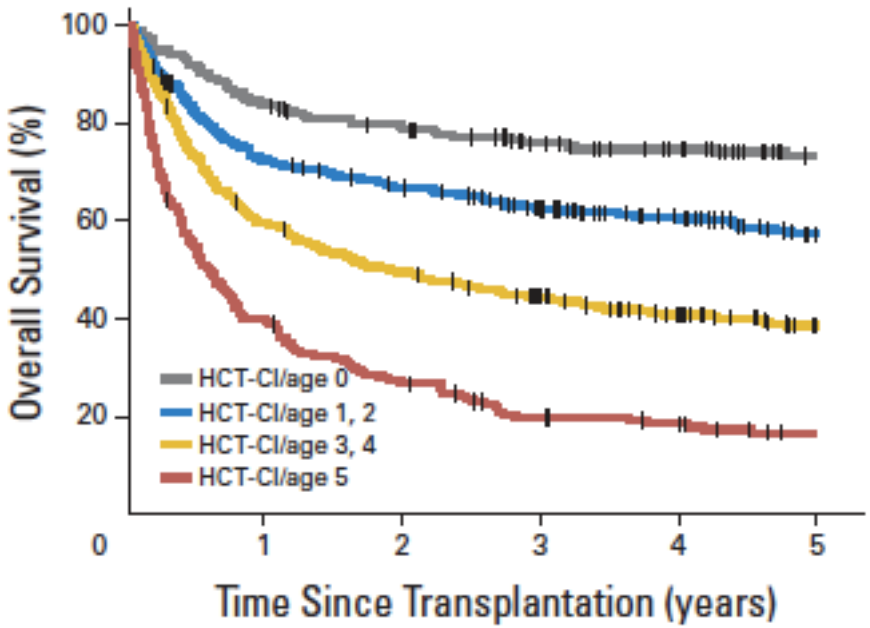
ORIGINAL REPORT

Comorbidity-Age Index: A Clinical Measure of Biologic Age Before Allogeneic Hematopoietic Cell Transplantation

Mohamed L. Sorror, Rainer F. Storb, Brenda M. Sandmaier, Richard T. Maziarz, Michael A. Pulsipher, Michael B. Maris, Smita Bhatia, Fabiana Ostronoff, H. Joachim Deeg, Karen L. Syrjala, Elihu Estey, David G. Maloney, Frederick R. Appelbaum, Paul J. Martin, and Barry E. Storer

http://www.hctci.org/Home/Calculator

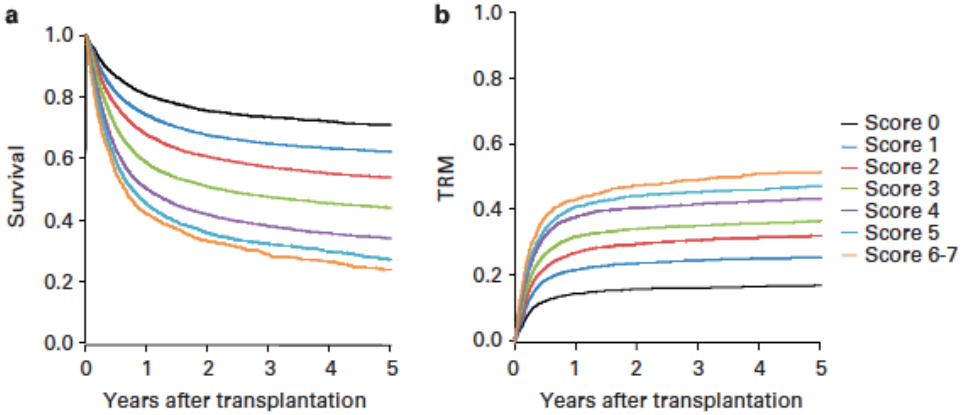


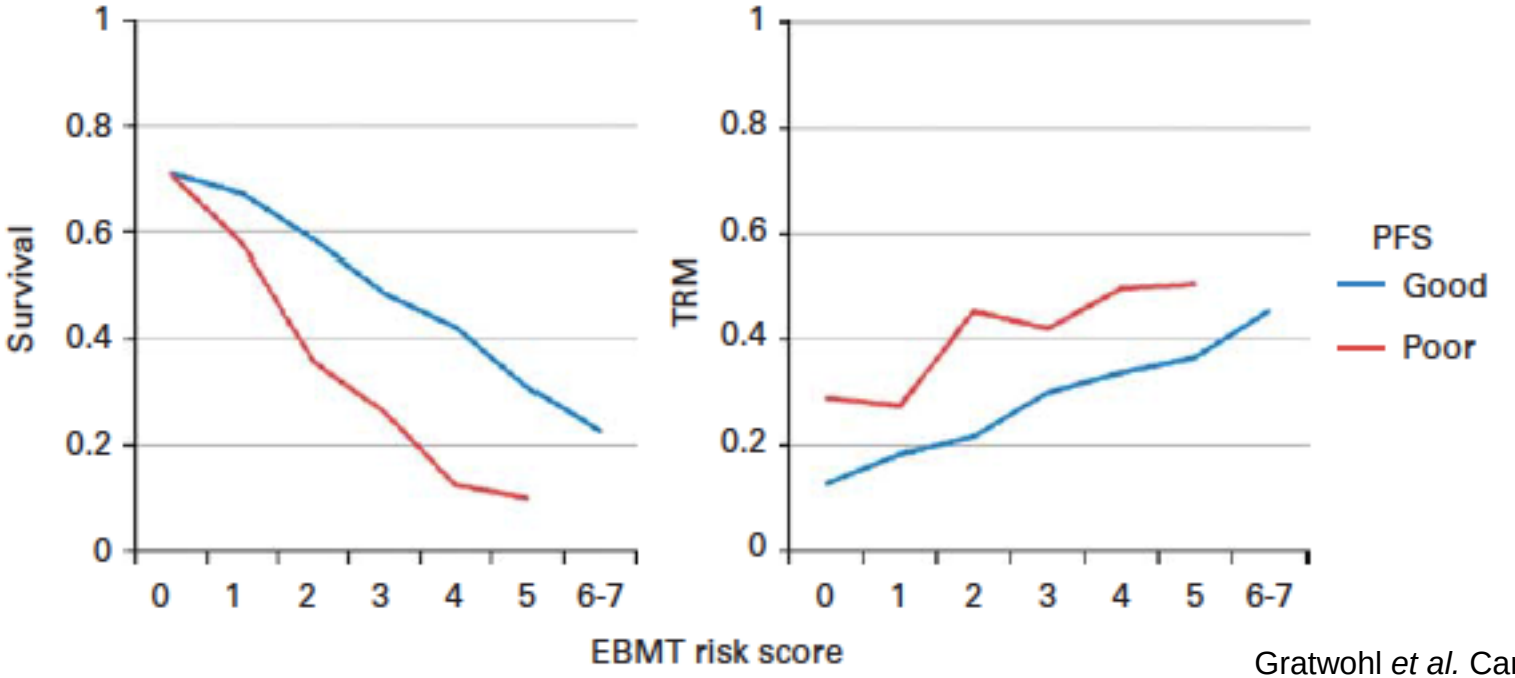


EBMT risk score

Table 1 EBMT risk score definition

Risk factor	*Score points*
Age of the patient, years	
<20	0
20–40	1
>40	2
Disease stage[a]	
Early	0
Intermediate	1
Late	2
Time interval from diagnosis to transplant, months[b]	
<12	0
>12	1
Donor type[c]	
HLA-identical sibling donor	0
Unrelated donor, other	1
Donor recipient sex combination[c]	
All other	0
Female donor, male recipient	1





Gratwohl *et al.* Cancer 2009

FRED HUTCH
CURES START HERE™

http://pamscore.org

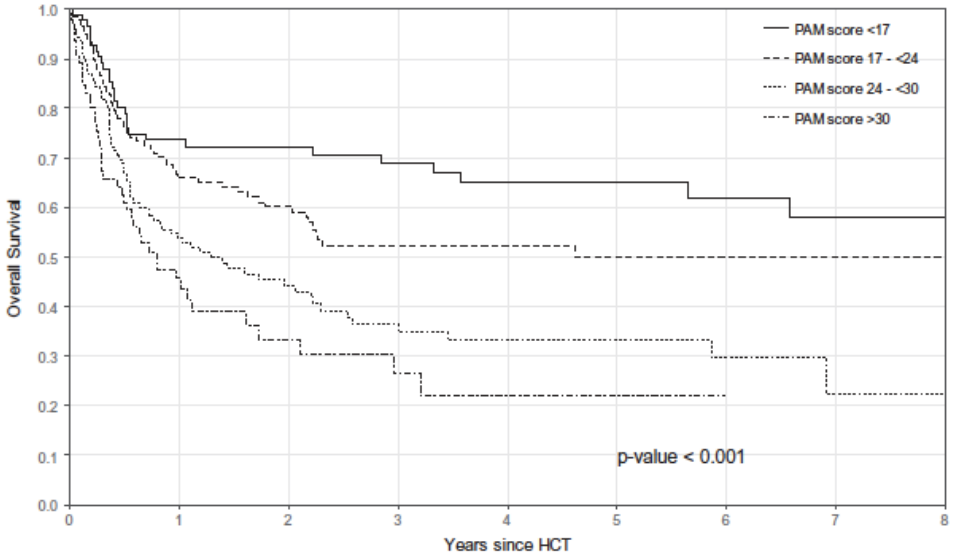
SEATTLE CANCER CARE ALLIANCE
Fred Hutchinson Cancer Research Center
UW Medicine
Seattle Children's

Pretransplant Assessment of Mortality Score

This calculator is designed to calculate a "PAM score" (Pretransplant Assessment of Mortality Score) that estimates the probability of survival at 2 years after allogeneic hematopoietic stem cell transplantation with myeloablative conditioning for treatment of a hematologic malignancy. The original scoring algorithm was developed and validated using a large cohort (1990 to 2002) at the Seattle Cancer Care Alliance/Fred Hutchinson Cancer Research Center (Annals of Internal Medicine, 2006 Mar 21;144(6):407-14). We recently published a study re-evaluating and revising the PAM model using a contemporary cohort (2003-2009) to update and recalibrate its predictive capability (Au et al., Biology of Blood and Marrow Transplantation. 2015; in press). The results below reflect the updated PAM model.

To use this calculator, enter data for the nine clinical and laboratory variables below using the drop down menus.

- Paciente
- Donante
- Enfermedad y riesgo



Middeke *et al.* BBMT 2018

MA vs AIR: HGUGM 2018

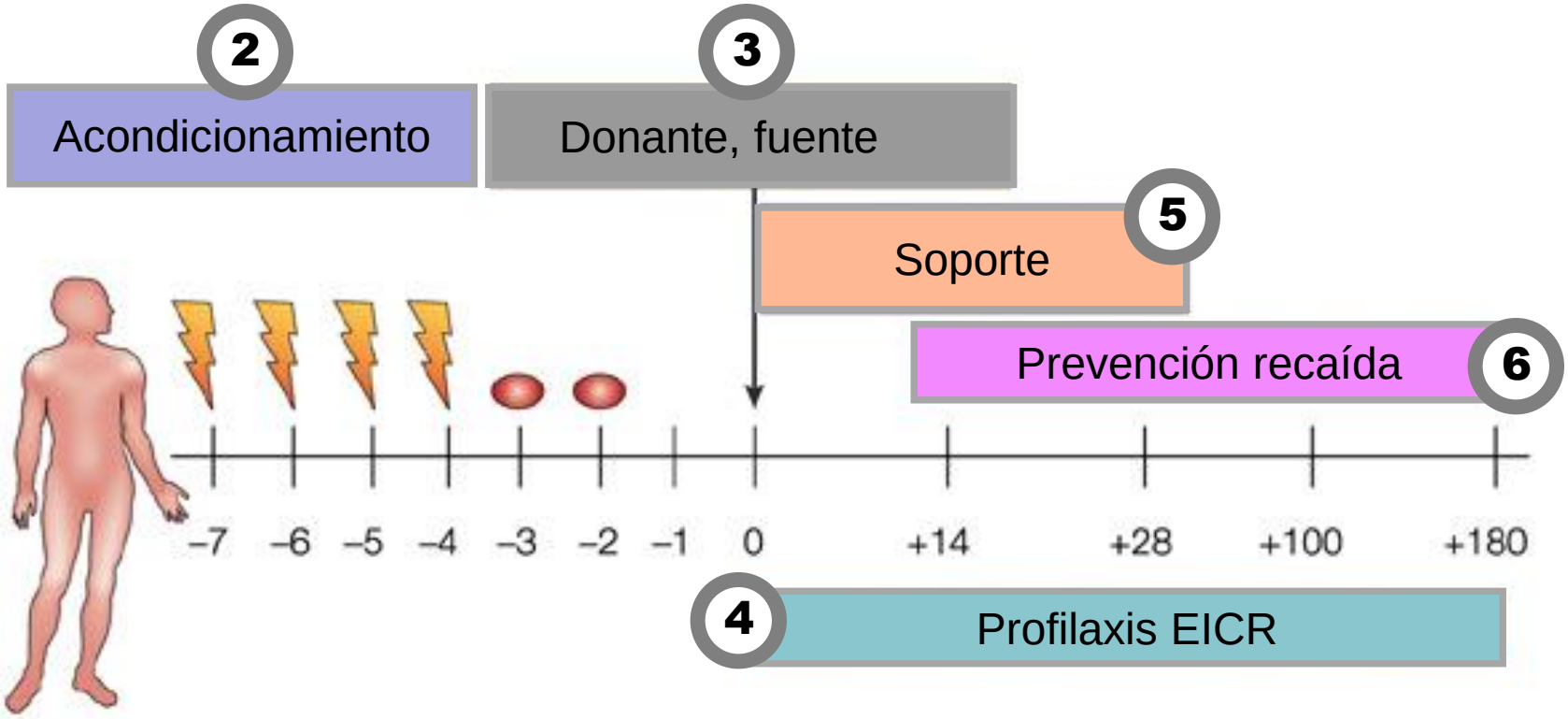
AIR

- Edad >60 años
- Indice de comorbilidad ≥3
- Patología linfoproliferativa
- MM

MA

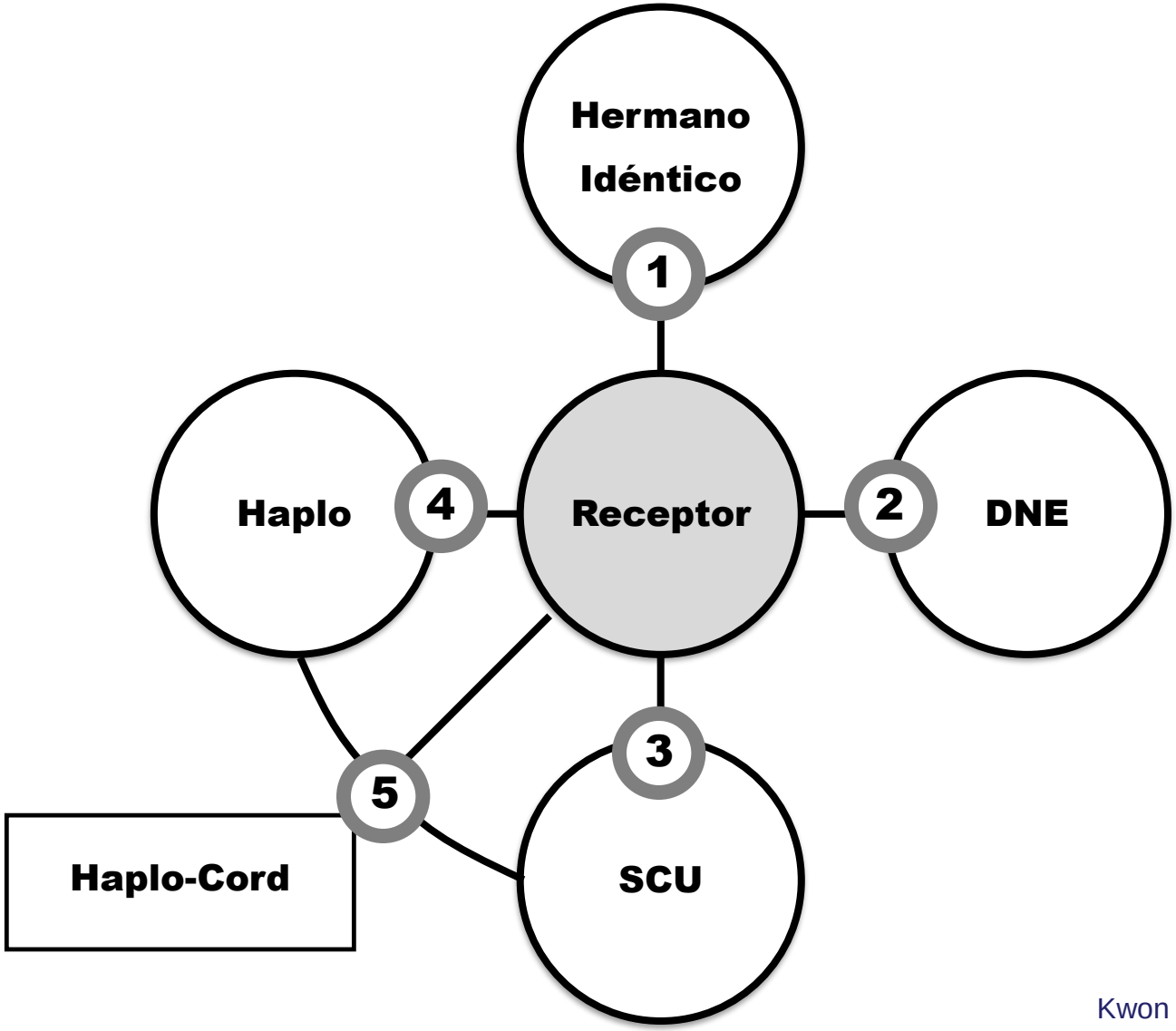
- Edad hasta 60 años
- Indice de comorbilidad <3
- Leucemia aguda
- SMD
- Aplasia medular
- Enfermedad activa

El TPH alogénico



Adaptado de M Bleakley, S Riddell. Nature Reviews Cancer 4, 2004

Donantes para TPH alogénico



Kwon *et al*. Acta Cient Tecnol 2014

Limitaciones

Hermanos: tamaño de las familias, limitado en pacientes mayores

DNE: etnicidad

Cordón: costos, experiencia

Haplo: anticuerpos donante específicos

Urgencia

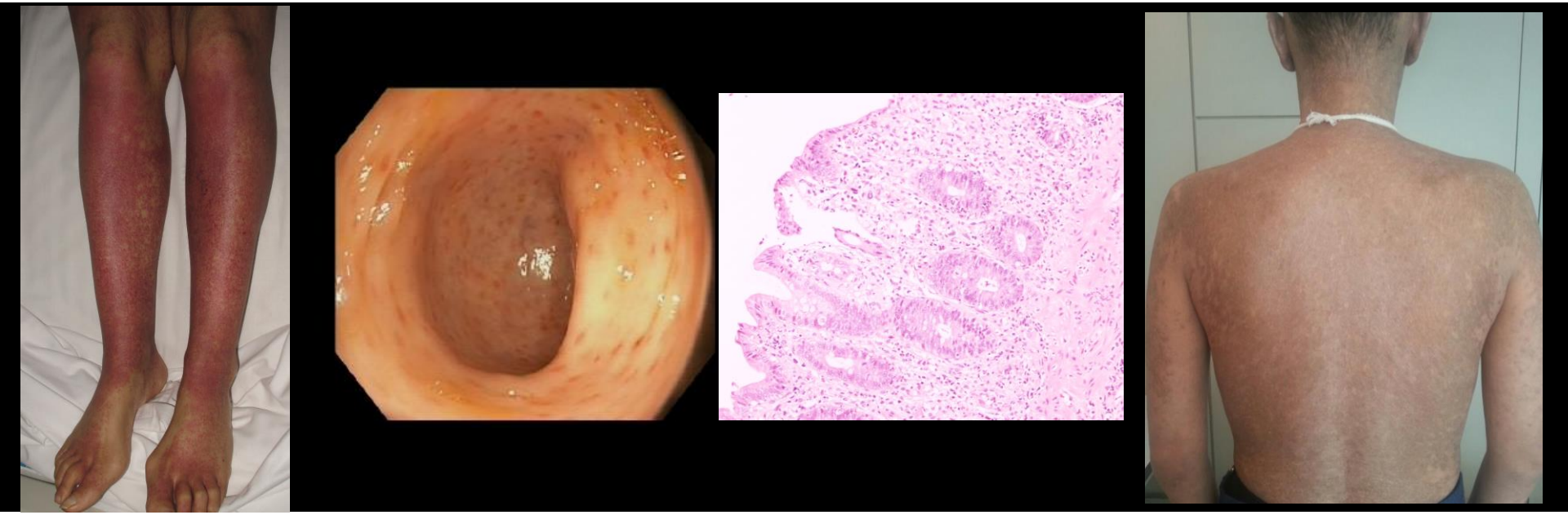
Disponibilidad

Hermano HLA-id ≅30%

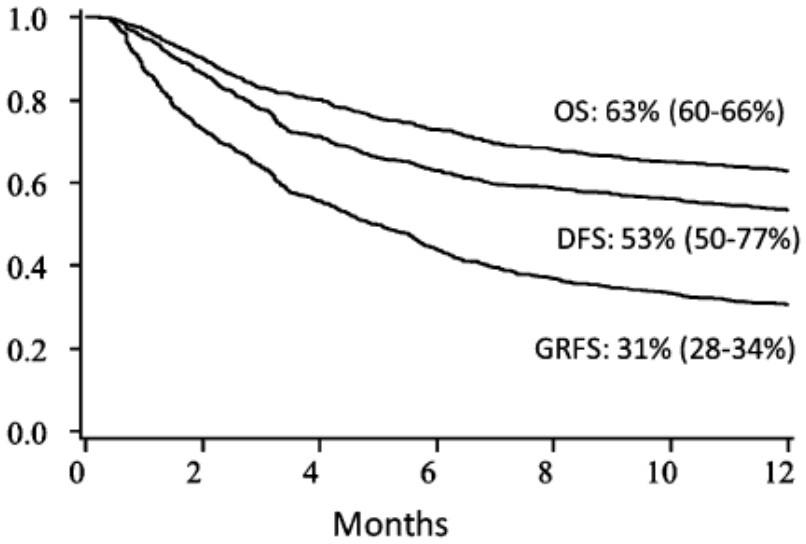
DNE	50%
Cordón	90%
Haploidéntico	>90%

"n" siblings	$1 - (0.75)^n$
1 sibling	$1 - (0.75)^1 = 0.25$
2 siblings	$1 - (0.75)^2 = 0.44$
4 siblings	$1 - (0.75)^4 = 0.68$
7 siblings	$1 - (0.75)^7 = 0.87$
1.3 siblings	$1 - (0.75)^{1.3} = 0.30$

EICR aguda y crónica

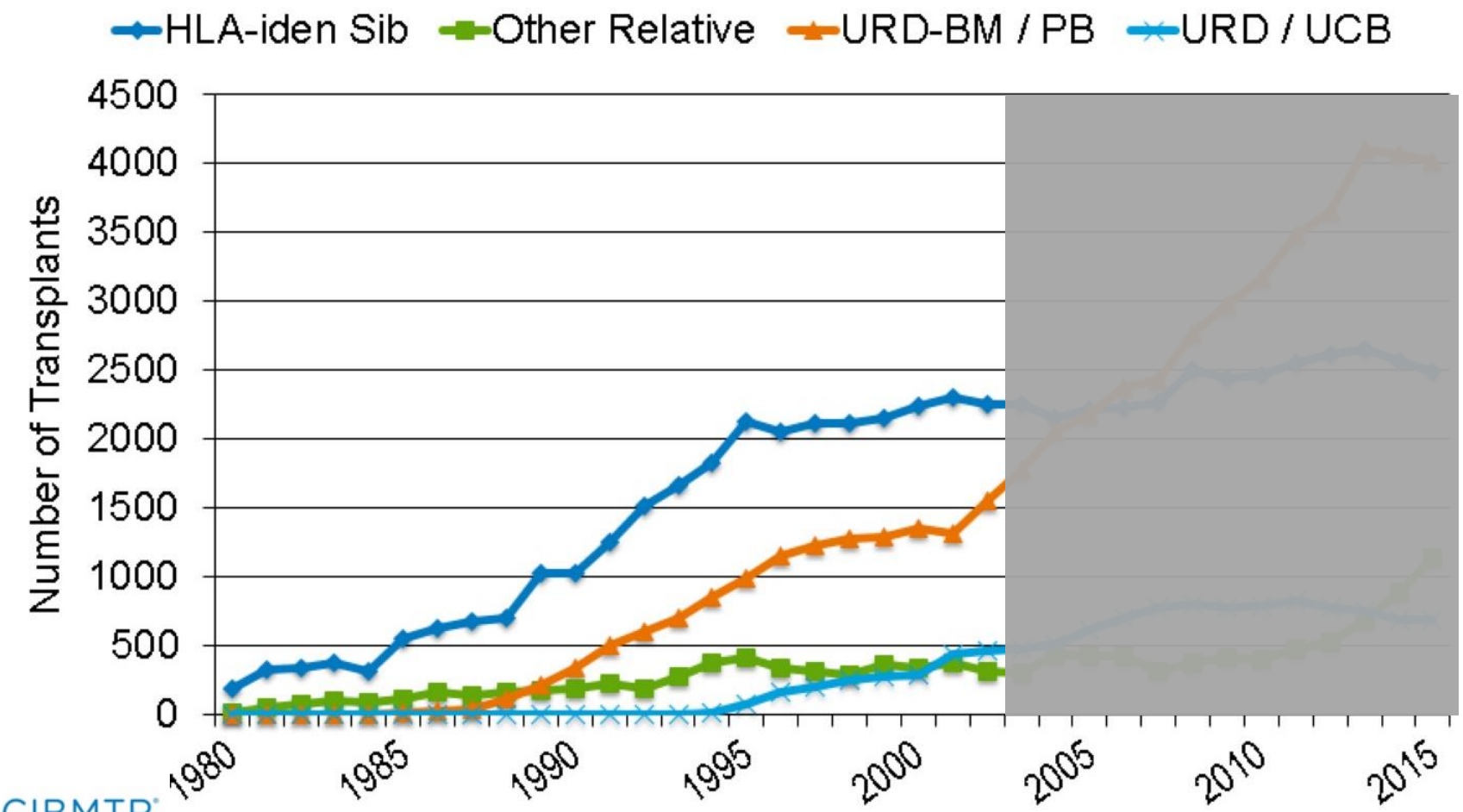


End-point compuesto:
“ GRFS “
Supervivencia libre de recaída y de EICR



Holtan *et al.* Blood 2015

Hermano HLA-id: donante de elección



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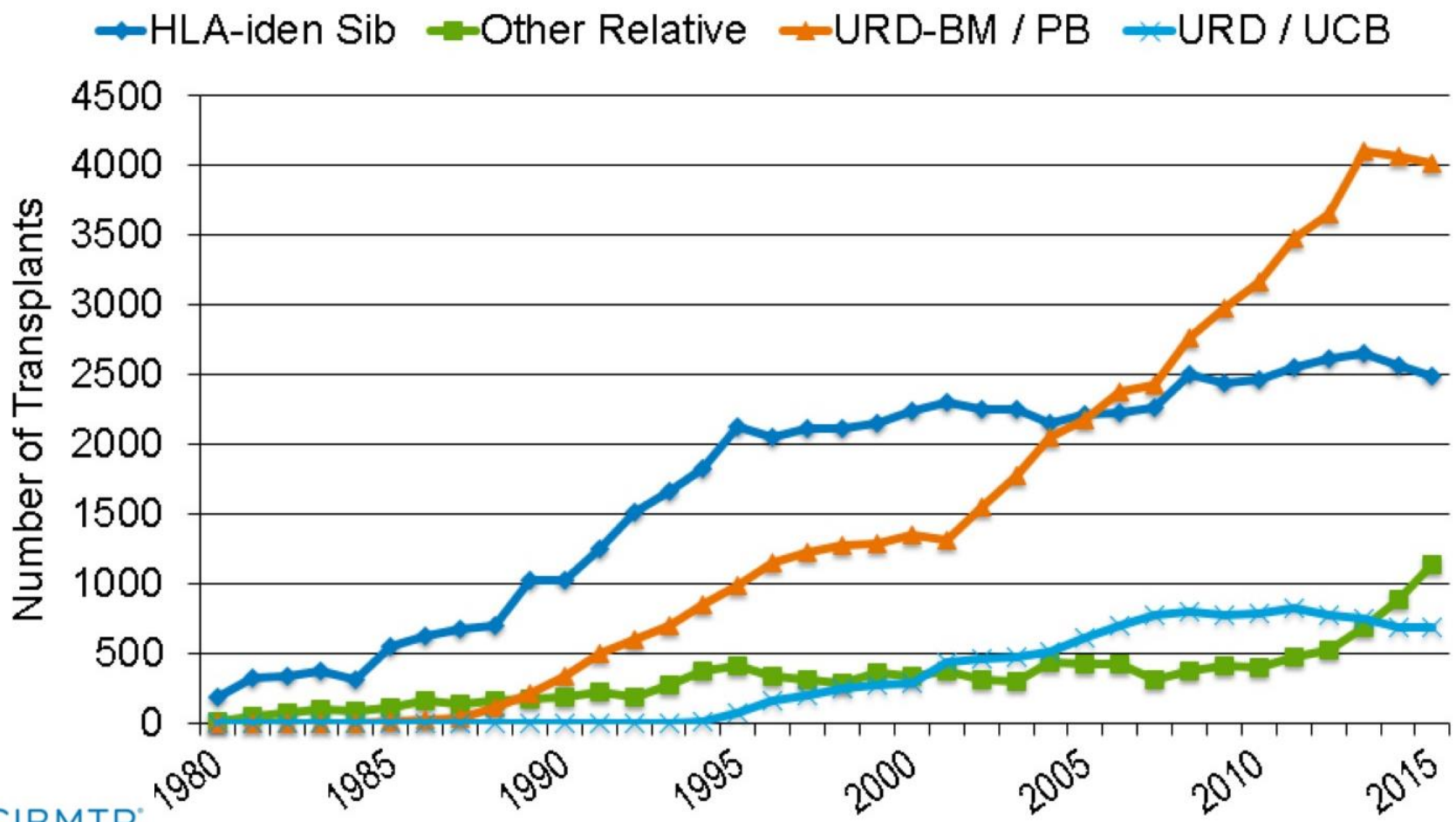
Hermano HLA-id: donante de elección



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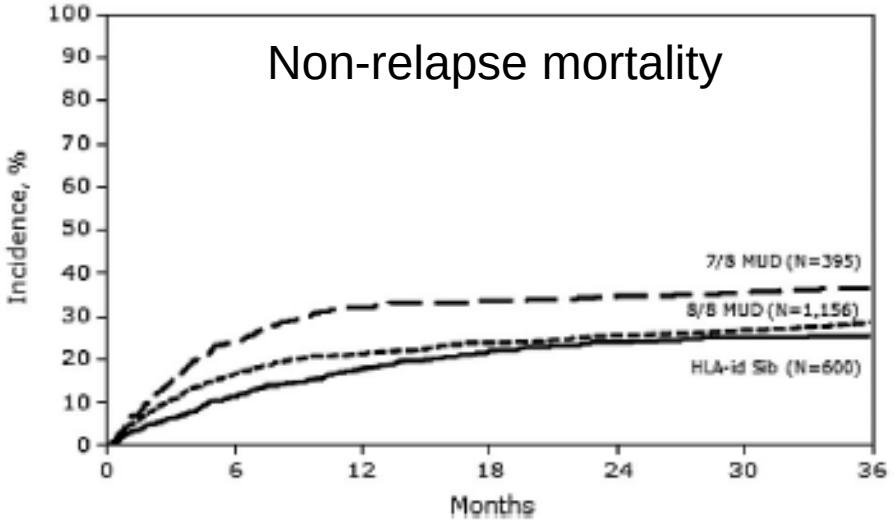
Hermano HLA-id vs DNE HLA-id

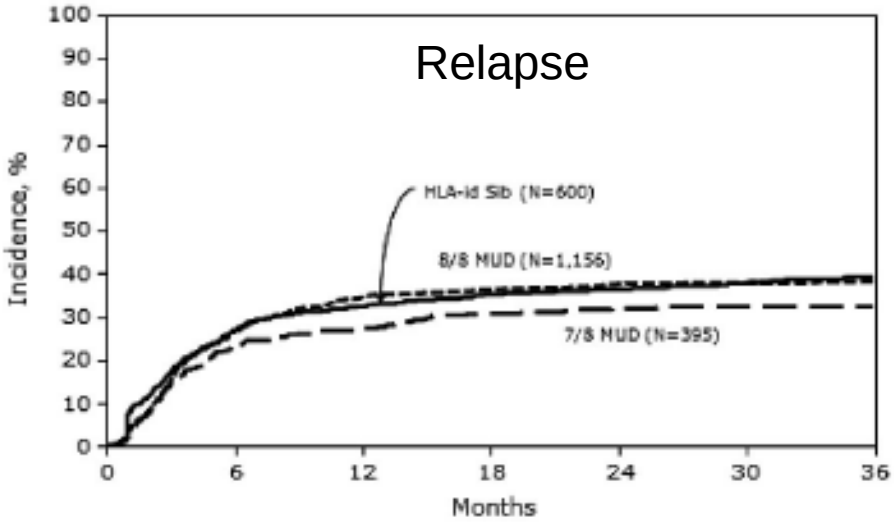
Outcomes after matched unrelated donor versus identical sibling hematopoietic cell transplantation in adults with acute myelogenous leukemia

Wael Saber,[1] Shaun Opie,[2] J. Douglas Rizzo,[1] Mei-Jie Zhang,[1] Mary M. Horowitz,[1] and Jeff Schriber[3]

[1]Center for International Blood and Marrow Transplant Research, Milwaukee, WI; [2]Banner Blood and Marrow Transplant Program, Phoenix, AZ; and [3]Cancer Transplant Institute, Virginia G. Piper Cancer Center, Scottsdale, AZ

Blood 2012

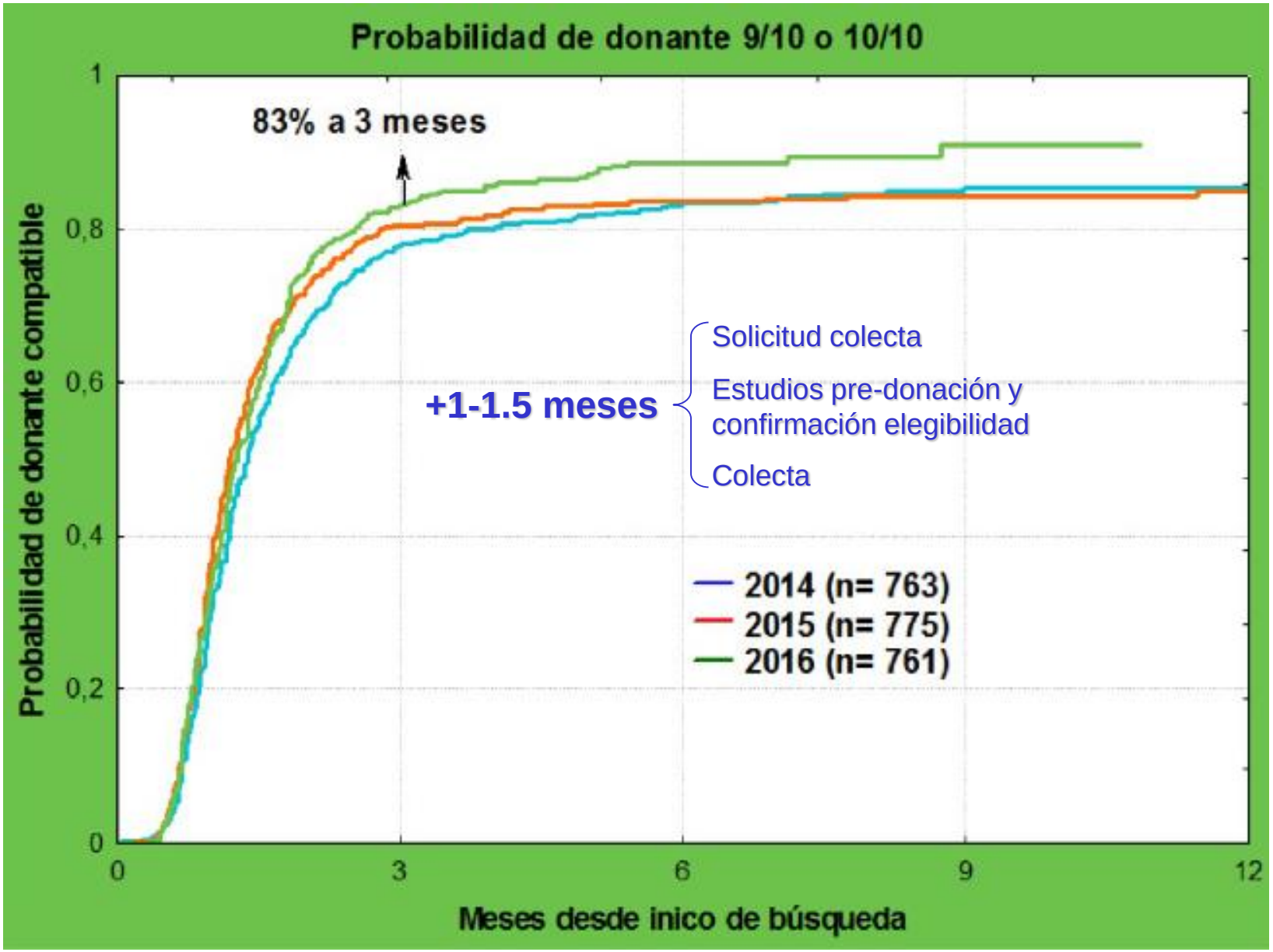




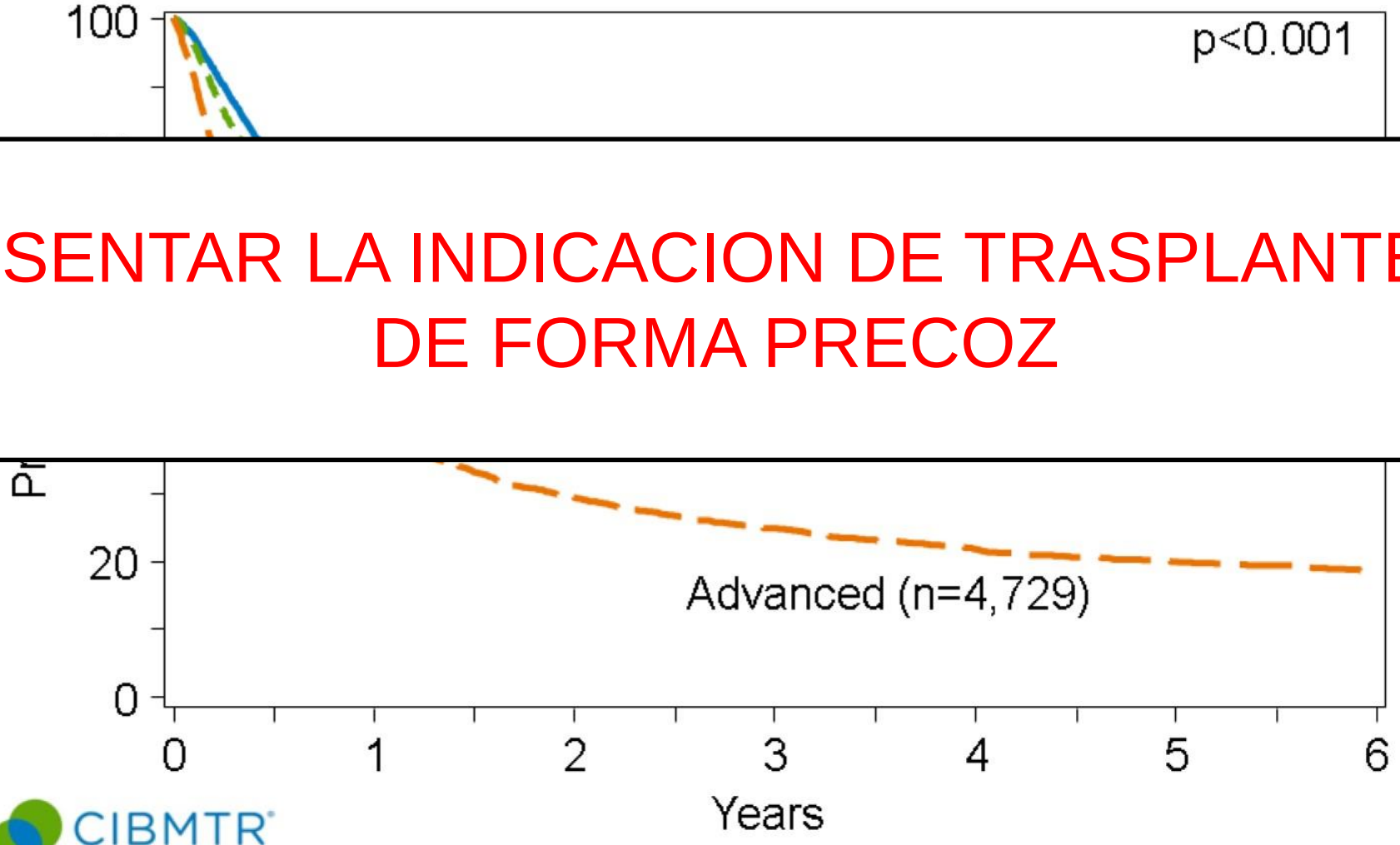
Criterios de selección donante no emparentado

- Identidad HLA
- Diferencia sexo D/R
- Incompatibilidad ABO
- Serología CMV D/R
- Edad del donante
- Anticuerpos anti-HLA en el paciente

REDMO 2016


Probabilidad de donante 9/10 o 10/10
83% a 3 meses
+1-1.5 meses
Solicitud colecta
Estudios pre-donación y confirmación elegibilidad
Colecta
2014 (n= 763)
2015 (n= 775)
2016 (n= 761)
Probabilidad de donante compatible
Meses desde inico de búsqueda
0
0,2
0,4
0,6
0,8
1
0
3
6
9
12

Survival after Unrelated Donor HCT for AML, 2004-2014



SENTAR LA INDICACION DE TRASPLANTE DE FORMA PRECOZ

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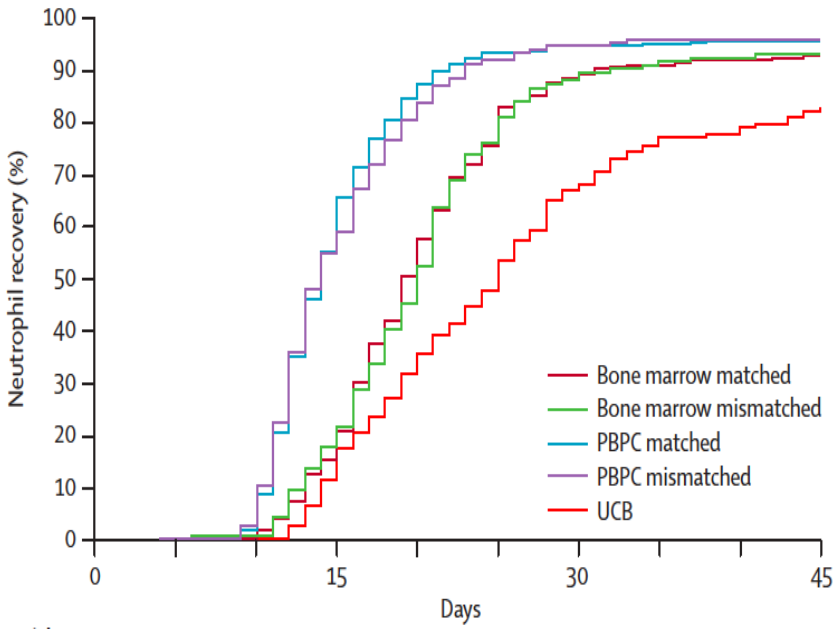
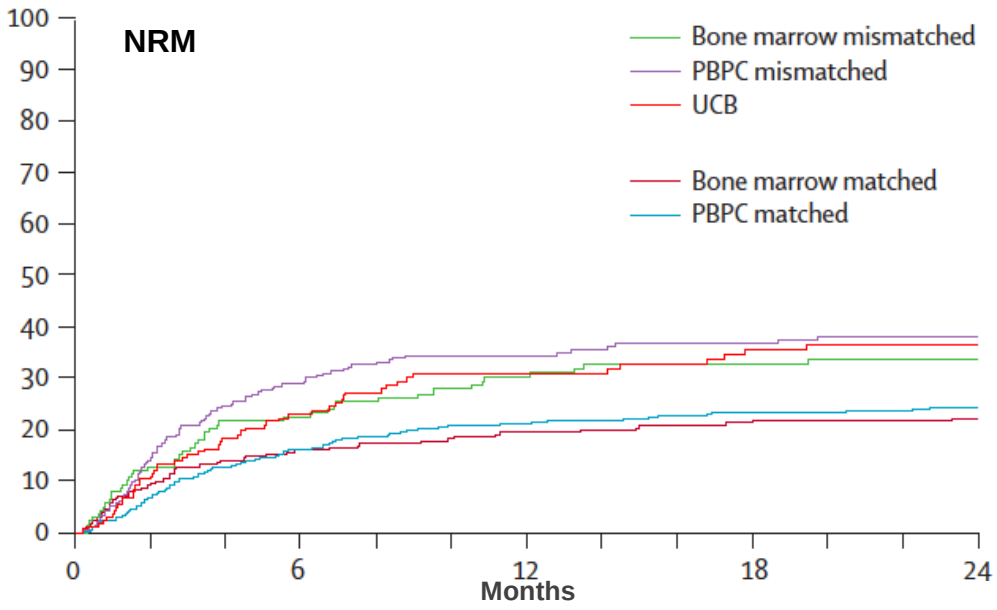
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Sangre de Cordón Umbilical





Principal limitación para su uso extendio en paciente adultos: prendimiento retardado por el número limitado de células infudidas

Eapen *et al.*, Lancet Oncol 2010

Los criterios de selección de SCU dependen de la estrategia de trasplante que se emplee

Pre-selección unidades

Id HLA ≥ 4/6 [A, B, DRB1]
TNC ≥ 2.5-3 x10^7/kg (min 1.500 x10^6)
CD34+ ≥1.5-2 x10^5/kg (min 10 x10^6)

Banco de origen

Anticuerpos anti-HLA

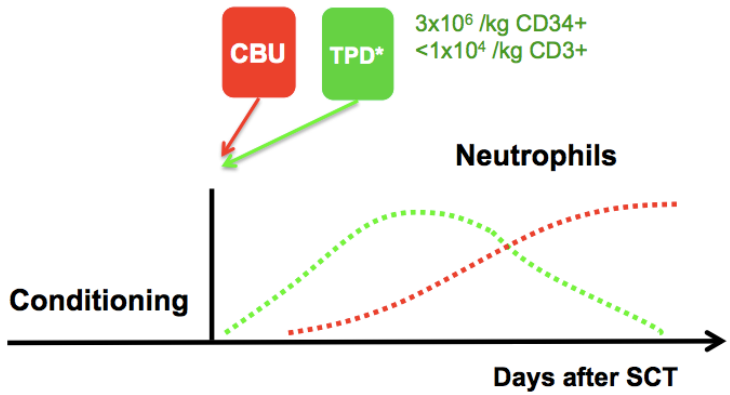
Incompatibilidad ABO

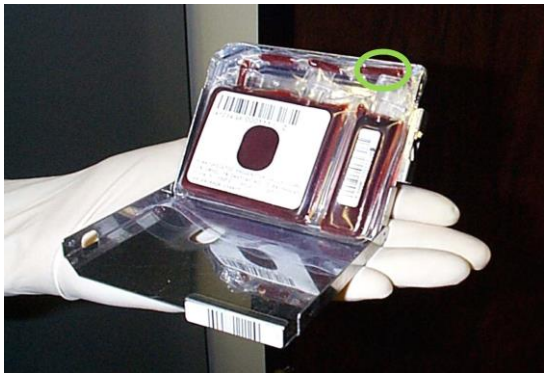
Solicitud informe

Estudios validación

Viabilidad, CFUs post-descongelación

TPH Dual o Haplo-Cord





Haplo-Cord Transplantation Using CD34^{+} Cells from a Third-Party Donor to Speed Engraftment in High-Risk Patients with Hematologic Disorders

Mi Kwon [1,*], Guiomar Bautista [2], Pascual Balsalobre [1], Isabel Sánchez-Ortega [3], David Serrano [1], Javier Anguita [1], Ismael Buño [1], Rafael Fores [2], Carmen Regidor [2], José A. García Marco [2], Carlos Vilches [4], Rosario de Pablo [4], Manuel N. Fernández [5], Jorge Gayoso [1], Rafael Duarte [3], José Luis Díez-Martín [1], Rafael Cabrera [2,5]

Biol Blood Marrow Transplant 20 (2014) 2015–2022

Biol Blood Marrow Transplant 19 (2013) 143–149

Single Cord Blood Combined with HLA-Mismatched Third Party Donor Cells: Comparable Results to Matched Unrelated Donor Transplantation in High-Risk Patients with Hematologic Disorders

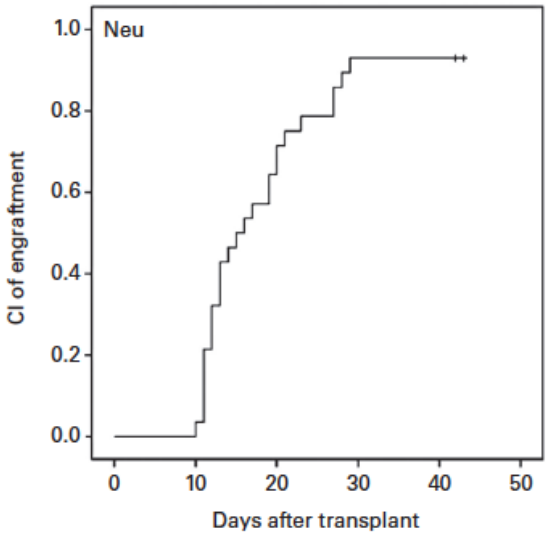
Mi Kwon [1,2,*], Pascual Balsalobre [1,2], David Serrano [1,2], A. Pérez Corral [2], Ismael Buño [1,2], Javier Anguita [1,2], Jorge Gayoso [1,2], Jose Luis Diez-Martin [1,2]

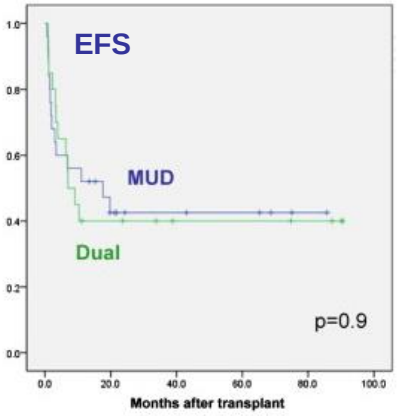
ORIGINAL ARTICLE

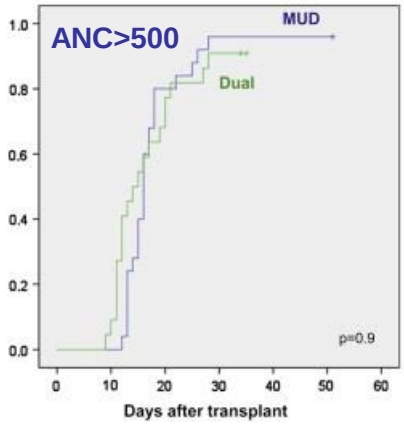
Early peripheral blood and T-cell chimerism dynamics after umbilical cord blood transplantation supported with haploidentical cells

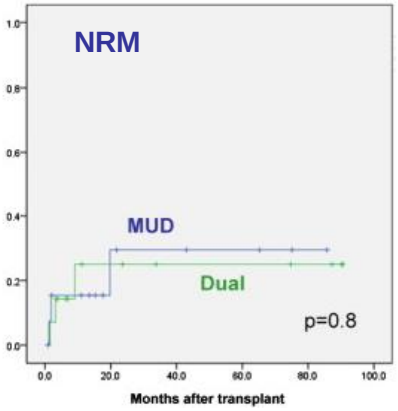
M Kwon, C Martínez-Laperche, P Balsalobre, D Serrano, J Anguita, J Gayoso, JL Díez-Martín and I Buño

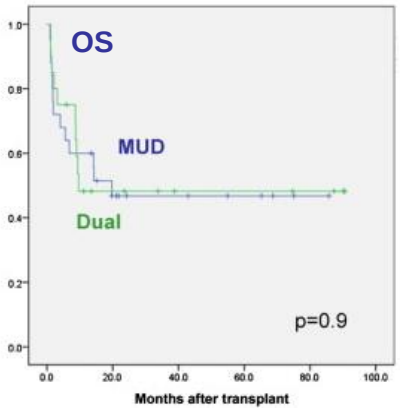
Bone Marrow Transplantation (2013), 1–7





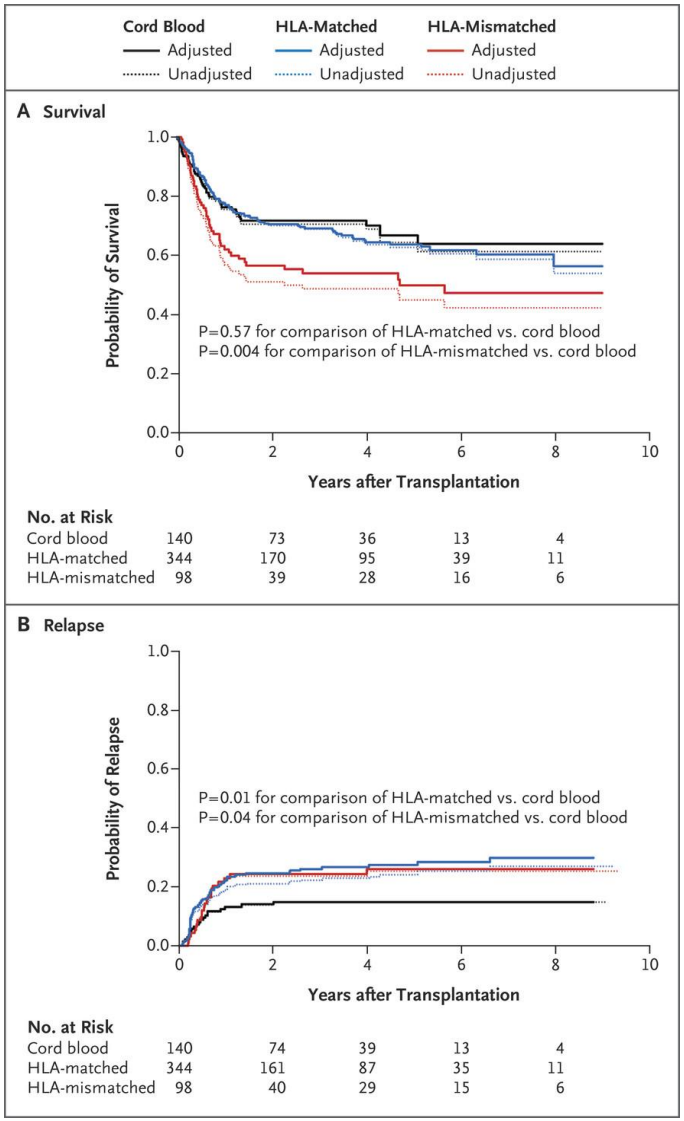






Cord-Blood Transplantation in Patients with Minimal Residual Disease

Filippo Milano, M.D., Ph.D., Ted Gooley, Ph.D., Brent Wood, M.D., Ann Woolfrey, M.D., Mary E. Flowers, M.D., Kristine Doney, M.D., Robert Witherspoon, M.D., Marco Mielcarek, M.D., Joachim H. Deeg, M.D., Mohamed Sorror, M.D., Ann Dahlberg, M.D., Brenda M. Sandmaier, M.D., et al.



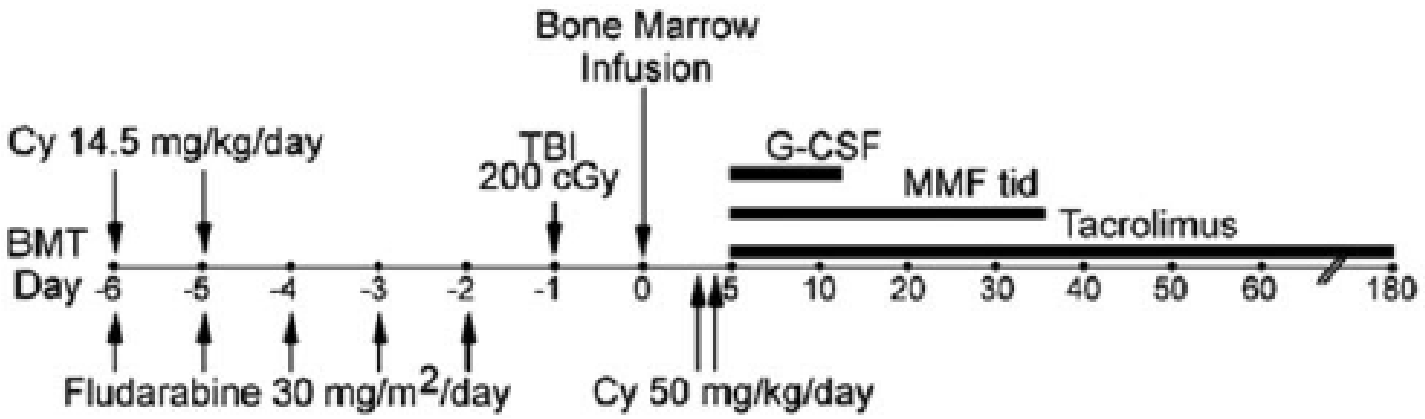
Milano F *et al.* N Engl J Med 2016;375:944-953.

Donate Haploidéntico

- Prácticamente todos tenemos por lo menos un familiar parcialmente compatible (padres, hermanos, hijos)
- Los resultados con trasplante haploidéntico para la mayoría de neoplasias malignas son al menos comparables a día de hoy con otras fuentes
- Los regímenes que no requieren manipulación *in vitro* del inóculo han facilitado enormemente su aplicación

Ciclofosfamida post-trasplante

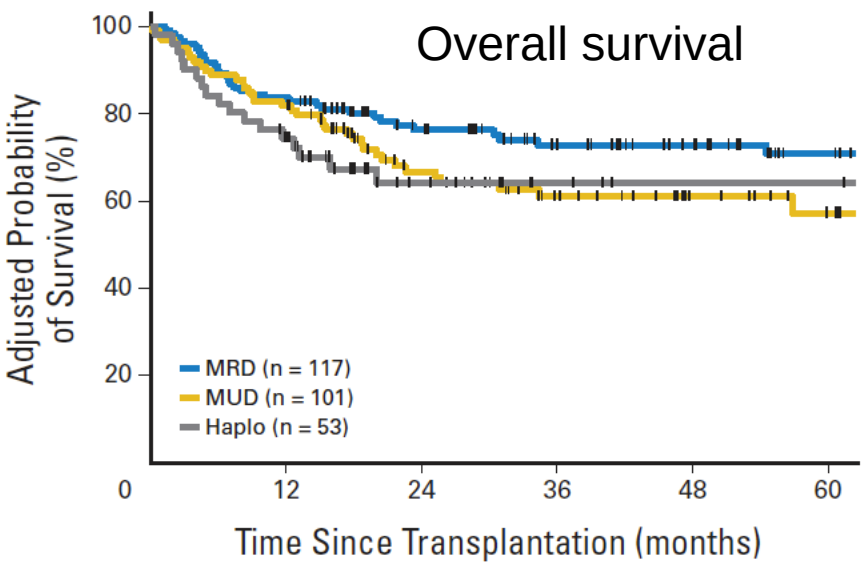
HLA-Haploidentical Bone Marrow Transplantation for Hematologic Malignancies Using Nonmyeloablative Conditioning and High-Dose, Posttransplantation Cyclophosphamide

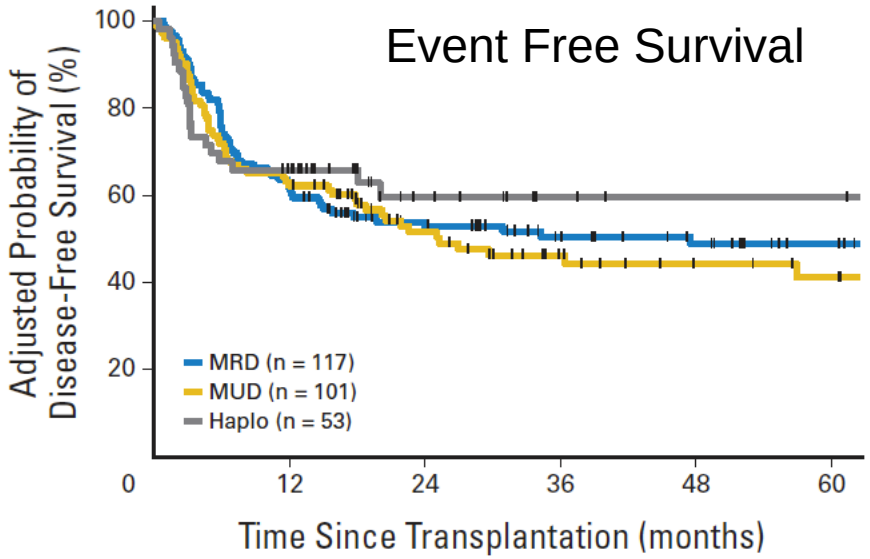


Uso extendido en todo el mundo

Guinan E, *et al.* BBMT 2010; Luznik L, *et al*. BBMT 2008

Haplo CYPT vs Hermano y DNE idéntico





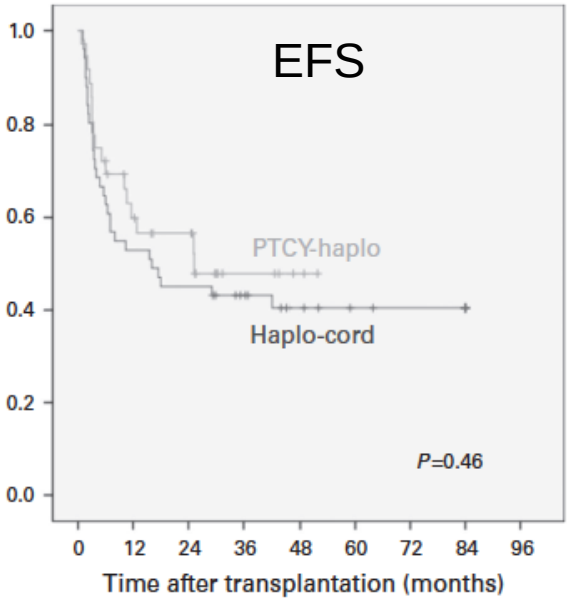
Kanakry *et al*. JCO 2016

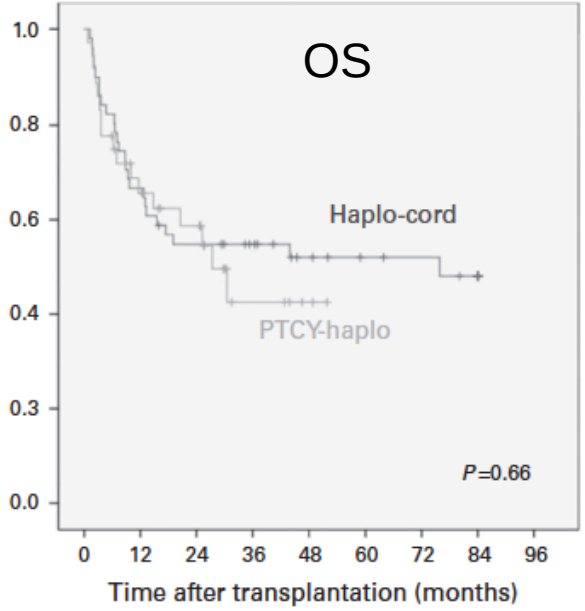
Haplo vs Haplo-Cord

ORIGINAL ARTICLE

Haplo-Cord transplantation compared to haploidentical transplantation with post-transplant cyclophosphamide in patients with AML

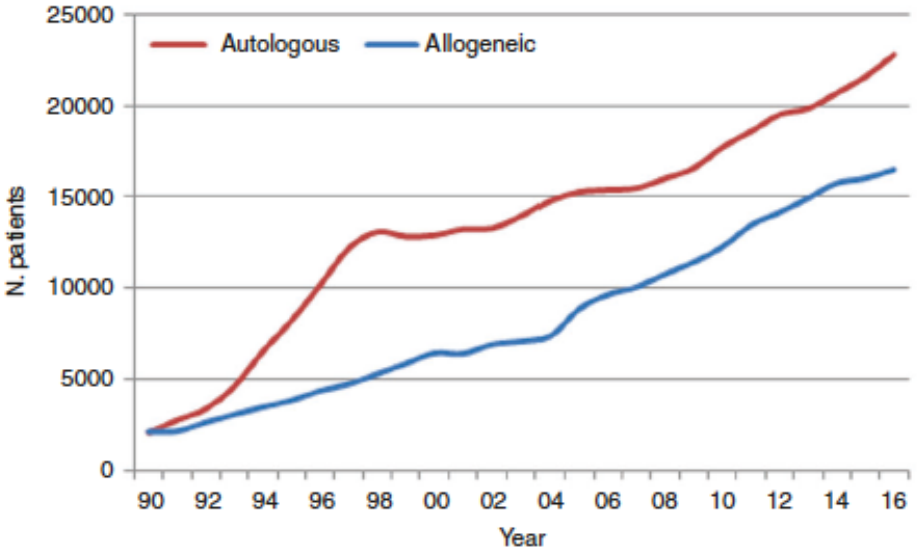
M Kwon[1,2], G Bautista[3], P Balsalobre[1,2], I Sánchez-Ortega[4], P Montesinos[5], A Bermúdez[6], A de Laiglesia[3], P Herrera[7], C Martin[8], K Humala[9], A Zabalza[10], M Torres[11], L Bento[12], LL Corral[13], I Heras[14], D Serrano[1,2], I Buño[1,2], J Anguita[1,2], C Regidor[3], R Duarte[3], R Cabrera[3], J Gayoso[1,2,15] and JL Diez-Martin[1,2,15] on behalf of Grupo Español de Trasplante Hematopoyético y Terapia Celular (GETH)

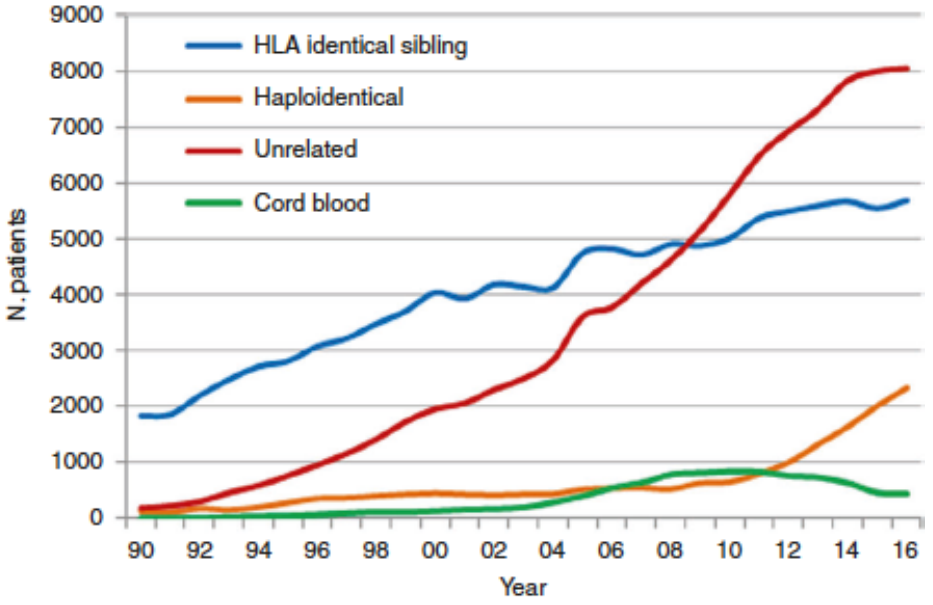




Bone Marrow Transpl 2017

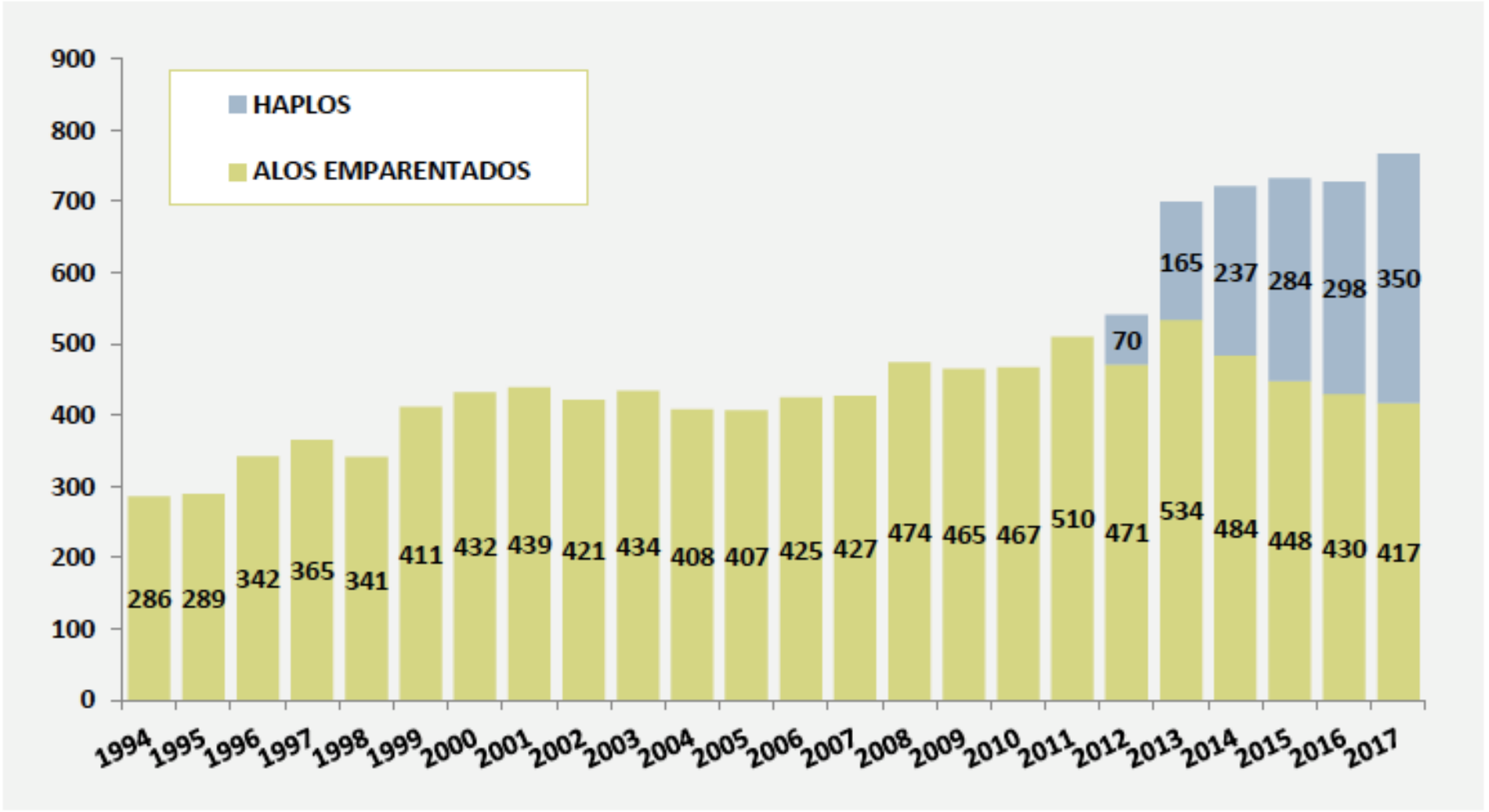
Is the use of unrelated donor transplantation leveling off in Europe? The 2016 European Society for Blood and Marrow Transplant activity survey report





Passweg *et al*. Bone Marrow Transpl 2018

TPH Haploidéntico en España



Selección de donante Haploidéntico

REVIEW

T-cell replete haploidentical donor transplantation using post-transplant CY: an emerging standard-of-care option for patients who lack an HLA-identical sibling donor

A Bashey and SR Solomon

Bone Marrow Transplantation (2014) **49,** 999–1008

1. **Anticuerpos ANTI-HLA**
2. **Mayor disparidad HLA**
3. **KIR aloreactivo**
4. **Donante más joven**
5. **Varón→ Varón (evitar madres)**

Table 3. Donor selection for haploidentical transplantation using post-transplant CY

1. Screen recipient for antibodies targeting mismatched donor HLAs (donor-specific antibodies, DSA)

- Screen all potential donors using solid-phase immunoassay (SPI) and cross-match of receipient serum against donor T and B lymphocytes
- Select donors with negative spi screen or low-level positivity ($<$1000 mean fluorescence intensity, MFI); if no negative donors available, and a negative anti-donor cross-match
- Donors with a negative cross-match and positive SPI screen may potentially be desensitized[44] but such donors should only be used if the anti-donor cross-match is negative following desensitization and is safer when using non-myeloablative conditioning

2. Choose a HLA-haploidentical donor with the greatest number of mismatches with the recipient on the non-shared haplotype

- 4 of 8 HLA-A, B, C and DRB1 matched donors appear to have a lower relapse rate and no increase in GVHD or graft rejection when compared to 5 of 8 and 6 of 8 matched donors.[21] Thus, choose a haploidentical donor with the greatest number of HLA mismatches with the recipient on the non-shared haplotype

3. Killer immunoglobulin-like receptor (KIR) mismatch between donor and recipient may facilitate natural killer cell alloreactivity

- Donors mismatched for inhibitory KIR receptors may produce lower relapse risk[45]
- Patients homozygous for KIR 'group A' may have improved outcomes if the donor has at least one KIR 'group B' haplotype[45]
- Additional study of KIR mismatching is necessary before KIR groups can routinely be used in donor selection

4. Younger donors preferred

- e.g. choose a young adult over a sibling or parent donor if other factors are equal[46]

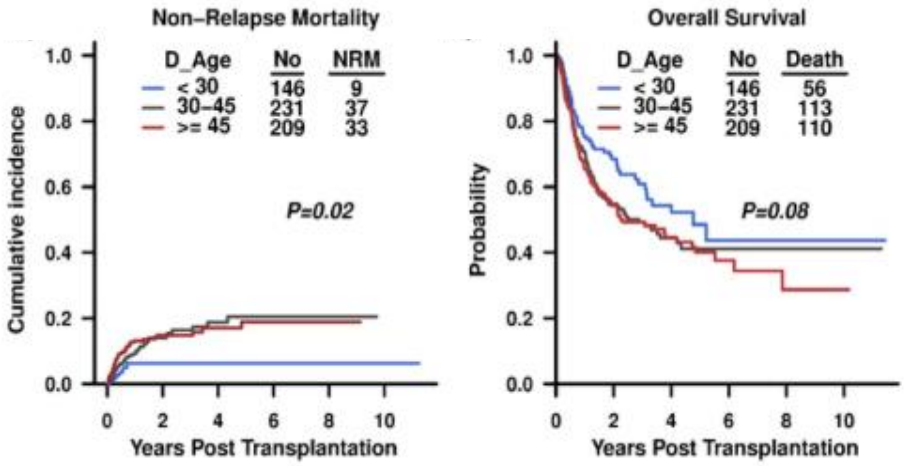
5. Male donors preferable particularly for male patients

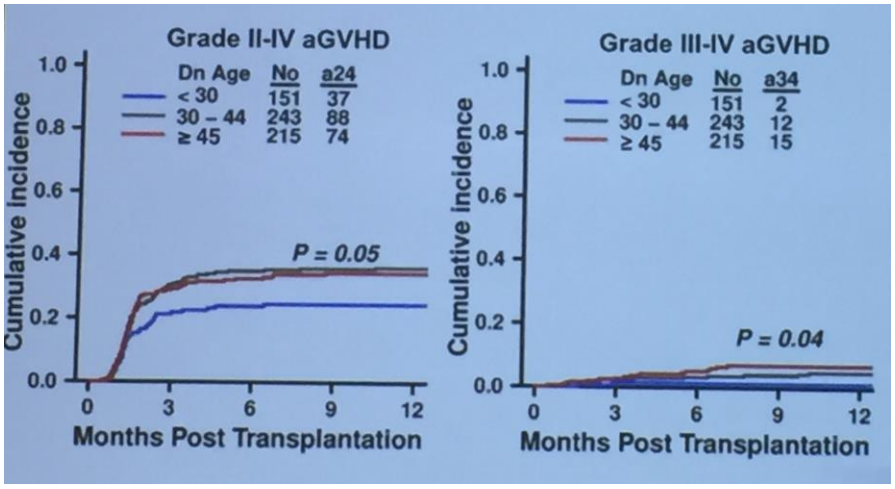
- Avoid mother as a donor unless no other choices[46]

CO 849 The Fountain of Youth: Outcomes of Nonmyeloablative, HLA-Haploidentical Related Bone Marrow Transplantation with Post-Transplantation Cyclophosphamide Best with Younger Donors Regardless of Relationship to Patient. Franklin *et al*, Johns Hopkins University

N = 609

Donante <30 años (n=151) vs 30-45 años (n=243) vs >45 años (n=215)





Priorizan edad (familiares de 2º grado)

Donante Haploidéntico: Limitaciones

- Número de integrantes de las familias
- Familia no disponible (USA)
- Anticuerpos donante específicos
- Recaída a largo plazo

Algoritmo: donantes alternativos HGUGM

Indicación Alo-TPH y no donante familiar HLA-id

Tipaje de alta resolución y búsqueda exploratoria inicial DNE en <60-65

ALO-TPH URGENTE:
- Fracaso de injerto
- Leucemias muy alto riesgo
- Leucemia retrasada

o

Linfoma Hodgkin ?

¿DNE HLA-id "a tiempo"? → SI → Alo-TPH DNE

NO ↓

¿Haplo? → SI → Haplo-TPH

NO ↓

¿SCU elegibles? → SI → Alo-TPH "Dual"

Id HLA ≥ 4/6
TNC ≥ 2.5-3 x10^7/kg (min 1500 x10^6)
CD34+ ≥1.5-2 x10^5/kg (min 10 x10^6)

El TPH alogénico

2

3

Urgencia

1 Patiente: edad, comorbilidades
Características de la enfermedad

Adaptado de M Bleakley, S Riddell. Nature Reviews Cancer 4, 2004

Conclusiones

- En la actualidad, la disponibilidad de donante no es una limitación para llevar a cabo un TPH alogénico
- Prioritario: establecer precozmente la indicación de trasplante y evitar retrasos en el inicio del procedimiento
- La selección del donante, fuente de progenitores y acondicionamiento depende de la estrategia global del procedimiento para cada paciente particular (edad, comorbilidad, tipo y estado de la enfermedad, etc) y de la experiencia del centro

Hospital General Universitario Gregorio Marañón

Comunidad de Madrid

Instituto de Investigación Sanitaria Gregorio Marañon

Preceptorship en Trasplante Alogénico

Del 4 al 8 de Febrero del 2019

Directora: Dra. Mi Kwon, Responsable del Programa de Trasplante de Progenitores
Coordinador: Dr. Pascual Balsalobre, Responsable de la Oficina de Coordinación de Trasplante

Dirigido a hematólogos especialistas o en formación del ámbito nacional e internacional interesados en profundizar en conocimientos actualizados y novedosos en trasplante hematopoyético alogénico

Formato del preceptorship: Presencial. Teórico. Práctico. Casos clínicos.

Duración y horario: 5 días consecutivos (Lunes a Viernes) de 8:00hs a 18:00hs.

Número de alumnos: 10, seleccionados con criterios estratégicos de oportunidad y motivación

mi.kwon@salud.madrid.org

Agradecimientos

Hematología-UTMO
José Luis Díez Martín
David Serrano
Pascual Balsalobre
Laura Solán
Nieves Dorado

Genética Hematológica
Ismael Buño
Carolina Martínez Laperche
María Chicano
Diego Carbonell

Unidad de Genómica
Ismael Buño
Julia Suárez

Unidad de Obtención, Procesamiento y Almacenamiento
Javier Anguita
Ana Pérez Corral
Cristina Pascual
Rebeca Bailén

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Grupo Español de Trasplante Hematopoyético y Terapia Celular

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