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TRANSPLANT STRATEGIES IN LOW-AND MIDDLE-INCOME COUNTRIES
THE SOUTH AFRICAN EXPERIENCE

Justin du Toit

Clinical haematologist

INCEPTION OF HAEMATOPOIETIC STEM CELL TRANSPLANT (HSCT) IN SA – 1970'S

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S Afr Med J. 1976 Apr 3;50(15):577-9.

Bone marrow reconstitution using a block grafting technique

J R Parker, S P Taylor, G Manuel, P Jacobs

PMID: 772828

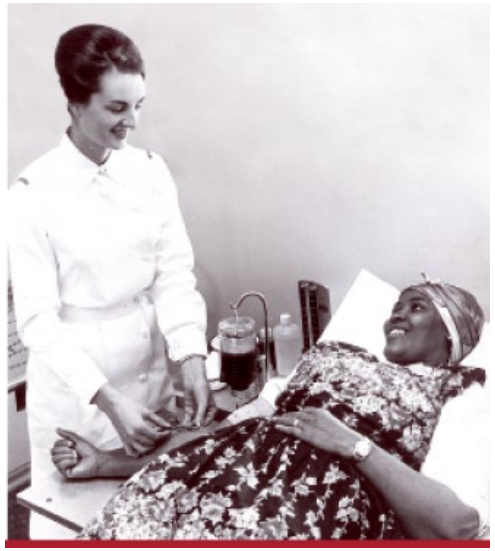
Abstract

Experiments in rabbits with radiation-induced bone marrow aplasia have demonstrated that intramedullary block grafting is a feasible procedure. This technique requires surgical interference and offers no advantage over intravenous reconstitution. We therefore suggest that it has no value in therapeutic bone marrow transplantation.

Parker JjR, Taylor SP, Manuel G, jacobs P.
tramedullary bone marrow reconstitution in the rabbit. S Aafr Surg 1975;13:186-187

Jacobs P. effect of cyclosporine on the incidence of graft-versus-host disease (GVHD) and survival of rabbits following allogeneic bone marrow transplantation. Iin: Baum Sj, Ledney GD, Khan A (eds). experimental hematology today 1981. Basel: Karger, 1981:87-96

FURTHER DEVELOPMENTS THAT FOLLOWED….



- PIONEERING THE USE OF APHERESIS TECHNOLOGY
  - Replacing the obsolete delivery of blood products in ***bottles (Horlicks milk bottles!)***
  - Platelets supplied as single units without any quality control
  - This finally permeated into commercial blood banks

- COLLABORATIVE RESEARCH with Cambridge and Oxford that defined a role for T-lymphocyte depletion using Campath in vitro by adding to bone marrow grafts

1974	1991	1997	2002	2015	2018	2021
1st HSCT performed by Prof Peter Jacobs	1st registry founded by Prof Ernette du Toit and Prof Peter Jacobs	1st MUD HSCT (PBSC Belgium donor)	SASCeTS founded	1st JACIE accredited HSCT facility	2nd Registry founded by The Sunflower Fund	The Sunflower Fund is incorporated into DKMS

HERMAN WALDMAN (OXFORD) & GEOFF HALE (CAMBRIDGE) PRODUCED CAMPATH 1978

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Immunologists invented monoclonal antibody development

Graft versus host disease (GVHD) – severe immunological disorder post bone marrow transplant

Good target of research!

Can Campath abrogate GVHD by eliminating T cells present in bone marrow grafts?

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- T cells can be depleted by using anti-CD 52 antibodies directed against the CD52 antigen found on T and B lymphocytes, monocytes and dendritic cells

- First:
  - Campath® I-M, a rat antibody - capable of dissolving T cells by activating complement
  - Was effective in preventing GVHD but caused graft rejection
- Second:
  - Campath® I-G developed for in vivo depletion of host cells to prevent rejection
- Third:
  - Ab humanised by genetic engineering to create Campath® 1-H (1988)

- Herman Waldman constituted a Campath® Users' Group of which Professor Peter Jacobs was a member

- "Haem Team" at UCT started using Campath® and formed part of the initial experience of its effect on transplant

Wood L, Haveman J, Juritz J, Waldman H, Hale G, Jacobs P. Immunohematopoietic stem cell transplantation in Cape Town: a ten-year outcome analysis in adults. Hematol Oncol Stem Cell Ther. 2009;2(2):320-32. doi: 10.1016/s1658-3876(09)50020-9.

SOUTH AFRICA – THEN (IN 70’S) & EVEN NOW, HAVE UNIQUE CHALLENGES

SA - HEAVY BURDEN OF DISEASE

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- SA faces a **quadruple** burden of disease
  - Communicable diseases (HIV and tuberculosis[TB])
  - Non-communicable diseases (obesity, diabetes, cardiovascular disease and cancer)
  - High maternal, neonatal and child morbidity and mortality
  - High levels of violence and trauma
- Non-communicable diseases account for 40.0% of the total disease burden
- TB and HIV accounted for 26.7% of all deaths in 2015 - TB being the leading cause of death

Mayosi BM, Flisher AJ, Lalloo UG, Sitas F, Tollman SM, Bradshaw D. The burden of non-communicable diseases in South Africa. Lancet 2009;374(9693):934–47

Pillay-van Wyk V, Msemburi W, Laubscher R, et al. Mortality trends and differentials in South Africa from 1997 to 2012: Second National Burden of Disease Study. Lancet Glob Heal 2016;4(9):e642–53.

CONTINUING SOCIOECONOMIC CHALLENGES AND INEQUALITY

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- According to the World Bank, 'South Africa remains a dual economy with one of the highest inequality rates in the world' with Gini index of 63 in 2021
- "measures the extent to which the distribution of income among households within an economy deviates from a perfectly equal distribution. A Gini index of 0 represents perfect equality, while an index of 100 implies perfect inequality"
- Based on this, we are the most unequal country in the world
- Unemployment at 32.5% at the end of 2020 remains a key challenge
- Exacerbated by the COVID-19 pandemic which saw the economy contract by 7% in 2020

The world bank. The world bank: South Africa Overview [Internet]. 2021 [cited2021 May 23].

World Population Review. Gini Coefficient by Country 2020 [Internet]. World Population Review. 2021 [cited 2021 Oct 12]. p. 1–8.

THE HEALTH CARE SECTOR UNFORTUNATELY NOT SPARED FROM INEQUALITY

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- The private health care sector serves 16% of the population
  - world-class therapies are accessible BUT depends on tier medical fund

- Public sector - accessed by 84% of the population
  - Limited resources
  - Therefore, most beneficial treatments are prioritized for the largest number of patients

Benatar S, Sullivan T, Brown A. Why equity in health and in access to health care are elusive: insights from Canada and South Africa. Glob Public Health. 2018;13:1533–57

Gordon T, Booysen F, Mbonigaba J. Socio-economic inequalities in the multiple dimensions of access to healthcare: the case of South Africa. BMC Public Health. 2020;20:289

- **GRAFT VERSUS HOST DISEASE** IN OUR POPULATION WILL LEAD TO POOR OUTCOMES
  - All factors described above
  - Public transport and frequent clinic visits, costly for patients
  - Poor living conditions (hygiene, fungal infections?)
  - Compliance with immunosuppressive therapy
  - Unique Infections in our context (TB)
  - Inundated public hospitals might limit needed supportive care

- CAMPATH-H1 (ALEMTUZUMAB) – was this or is this the solution for OUR population?
  - Was this Prof Peter Jacobs vision / idea / hunch ?

CAMPATH SEEMED BETTER VERSUS ATG – RIC CONTEXT (2011)

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- RIC – Allo (n= 1676)
  - Haematological malignancies
  - Flu – Cy
  - MRD or MUD

- Alemtuzumab vs. ATG vs. No
  - aGvHD II-IV: 19% vs. 38% vs. 40%
  - cGvHD II-IV: 24% vs. 40% vs. 52%
  - Relapse incidence 49% vs. 51% vs. 38% (bit higher)
  - DFS: 30% vs. 25% vs. 39%
  - OS: 50% vs. 38% vs. 46%

- Cautionary note for T-cell depletion

Impact of immune modulation with anti–T-cell antibodies on the outcome of reduced-intensity allogeneic hematopoietic stem cell transplantation for hematologic malignancies

Robert J. Soiffer,[1] Jennifer LeRademacher,[2] Vincent Ho,[1] Fangyu Kan,[3] Andrew Artz,[4] Richard E. Champlin,[5] Steven Devine,[6] Luis Isola,[7] Hillard M. Lazarus,[8] David I. Marks,[9] David L. Porter,[10] Edmund K. Waller,[11] Mary M. Horowitz,[2] and Mary Eapen[2]

ADDING CAMPATH DOES NOT TRANSLATE TO POORER OUTCOMES (2002)

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- Non-randomised, retrospective analysis:
  - Lymphoproliferative disorders (n= 129)
  - Peripheral blood stem cell grafts
  - RIC (melphalan + fludarabine)
  - CAMPATH 100 mg+ CSA
  - Vs Methotrexate (10mg/m2 x 3)+ CSA
  - Escalated doses of DLI allowed

- Higher GvHD on MTX group

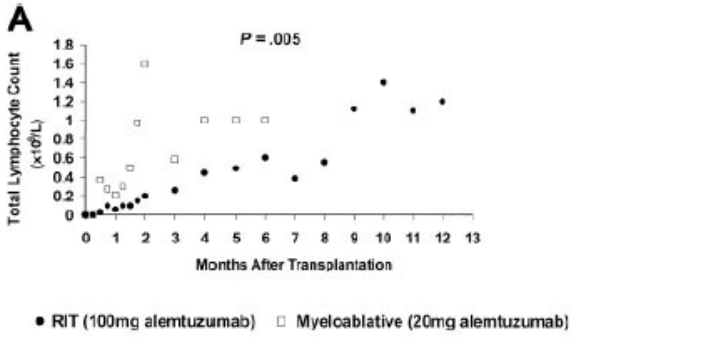
- Higher infections (CMV) & relapses in Campath group

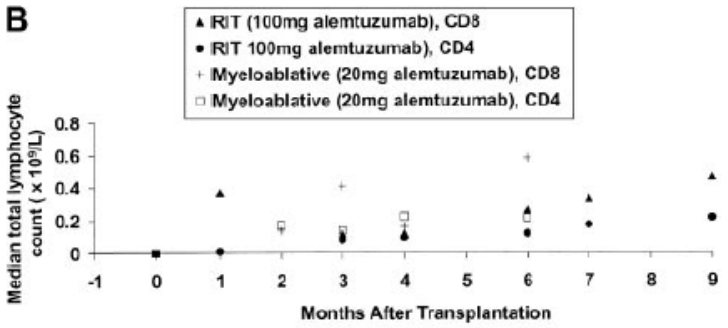
- But similar OS

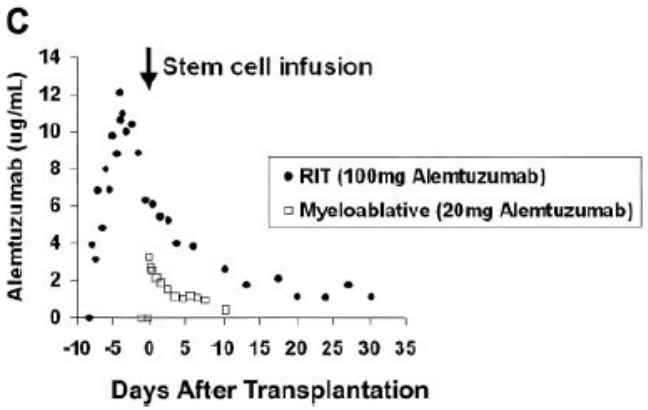
Nonmyeloablative transplantation with or without alemtuzumab: comparison between 2 prospective studies in patients with lymphoproliferative disorders

José A. Pérez-Simón, Panagiotis D. Kottaridis, Rodrigo Martino, Charles Craddock, Dolores Caballero, Raj Chopra, Javier García-Conde, Don W. Milligan, Stephen Schey, Alvaro Urbano-Ispizua, Anne Parker, Angel Leon, Kwee Yong, Ana Sureda, Ann Hunter, Jordi Sierra, Anthony H. Goldstone, David C. Linch, Jesus F. San Miguel, and Stephen Mackinnon, for the Spanish and United Kingdom Collaborative Groups for Nonmyeloablative Transplantation

PHARMACOKINETICS OF ALEMTUZUMAB – IN VIVO POOR IMMUNE RECONSTITUTION







- Stem cell transplantation (n= 10)
  - Compared in vivo + ex vivo
  - (Flu-Mel) + cyclosporin
  - 20 mg x 5 days (in vivo)
  - Vs in vitro alemtuzumab in RIT (20 mg in bag)
- Alemtuzumab concentrations in RIT remained at lympholytic levels for approx. 56 days post transplantation
  - 26 days longer vs myeloablative group
- Total lymphocyte counts significantly lower in the RIT group persisting > 6 months after transplantation (P < .005)
- Median ab CD4 counts > 200 were delayed 9 months after transplantation

Pharmacokinetics of alemtuzumab used for in vivo and in vitro T-cell depletion in allogeneic transplantations: relevance for early adoptive immunotherapy and infectious complications

Emma C. Morris, Peppy Rebello, Kirsty J. Thomson, Karl S. Peggs, Charalampia Kyriakou, Anthony H. Goldstone, Stephen Mackinnon, and Geoff Hale

UCT BMT results are comparable to those from established first world reference centers

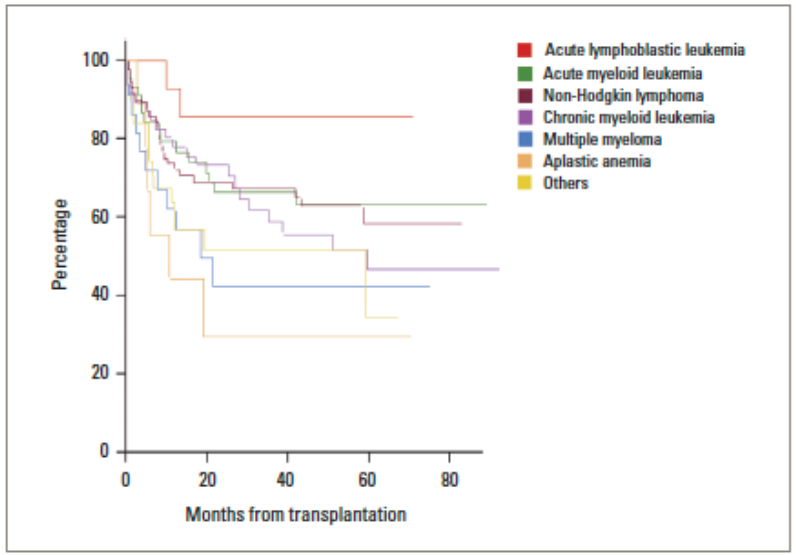


Figure 6. Outcome by diagnosis.

Table 1. Survival time in years from diagnosis.

Diagnosis	Number	Mean	Median	Minimum	Maximum
Acute myeloid leukemia	44	3.131	3.436	0.025	7.496
Acute lymphoplastic leukemia	14	3.301	2.929	0.814	5.923
Chronic myeloid leukemia	47	2.81	2.334	0.019	7.726
Lymphoma	71	2.764	3.142	0.011	6.94
Multiple myeloma	23	1.543	1.025	0	6.307
Aplastic anemia	10	1.433	0.697	0.074	5.885
Others	38	1.394	0.781	0.014	5.66

Immunohematopoietic stem cell transplantation in Cape Town: a ten-year outcome analysis in adults

Lucille Wood,[ab] Jonathan Haveman,[c] June Juritz,[c] Herman Waldmann,[d] Geoffrey Hale,[d] Peter Jacobs[abce]

From the [a]Division of Clinical Haematology, Department of Internal Medicine, Faculty of Health Sciences, Stellenbosch University–Tygerberg Academic Hospital, [b]the Department of Haematology and Bone Marrow Transplant Unit, The Searll Research Laboratory for Cellular and Molecular Biology, Constantiaberg Medi-Clinic, Burnham Road, Plumstead, [c]University of Cape Town, Cape Town, South Africa, [d]Sir William Dunn School, University of Oxford, Oxford, United Kingdom, and [e]College of Medicine, University of Nebraska, Nebraska, USA

Correspondence: Peter Jacobs, PhD · Constantiaberg Medi-Clinic, PO Box 294, Plumstead 7800, Cape Town, South Africa · T: + 27-21-7992566 F: +27-21-7614278 · haematol@icon.co.za · Accepted for publication June 2009

Hematol Oncol Stem Cel Ther 2009; 2(2): 320-332

- Ex vivo T-cell depletion is the seminal observation that survival curves are stable and do not have late and unrecognised sequelae vs those generated in recipients exposed to conventional immmunosuppressive regimens
- There is no apparent impact of this unique immunosuppressive regimen on developing myelodysplasia or predisposing to chronic infections (like TB)
- It remains to be determined whether the slightly higher incidence of CMV translates into any clinically important requirements other than proactive antiviral therapy

BUT NOW CAMPATH IN THE BAG NEEDED (AND LIKELY STILL NEEDS) MORE REFINEMENT

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- What is the optimal graft cell concentration?
- Most ideal Campath antibody dose?
- The *definite* need for complement?
- Whether alemtuzumab is infused with the graft during transplantation?
  - Impact on immune-reconstitution
  - Graft versus leukaemia effect

CAMPATH DEPLETES CD4 AND CD8 EFFECTIVELY, SPARES CD34 CELLS

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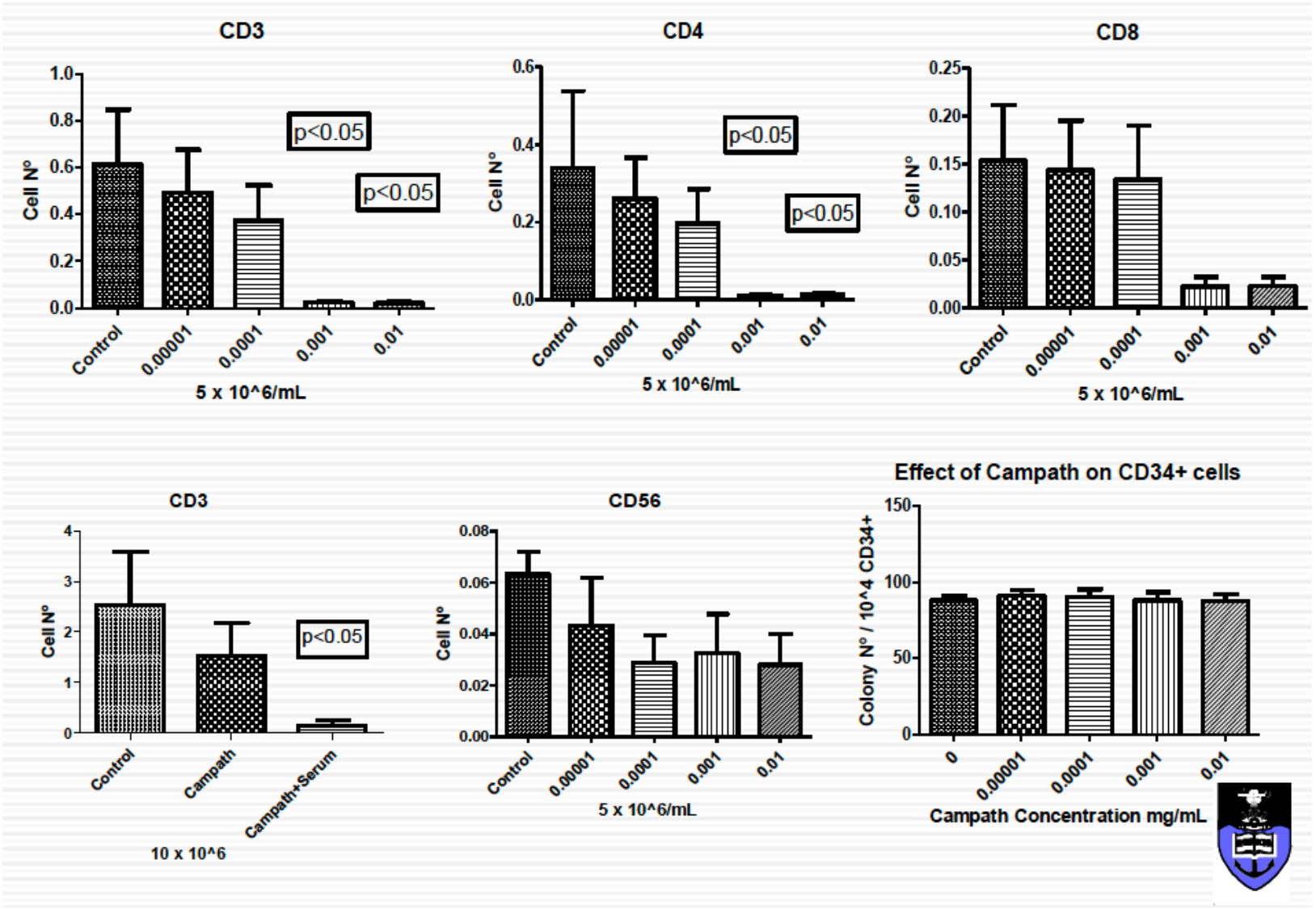
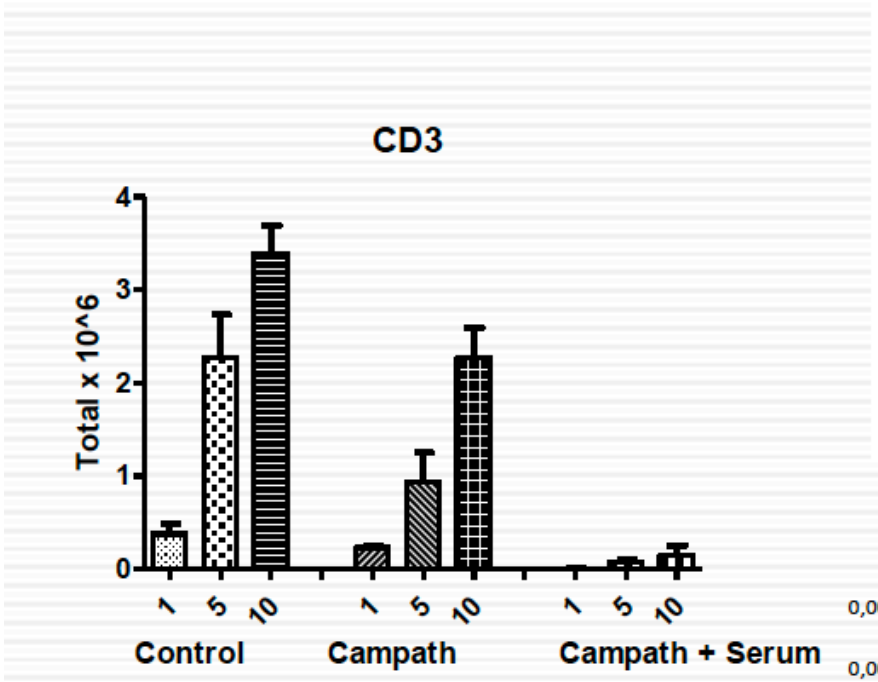


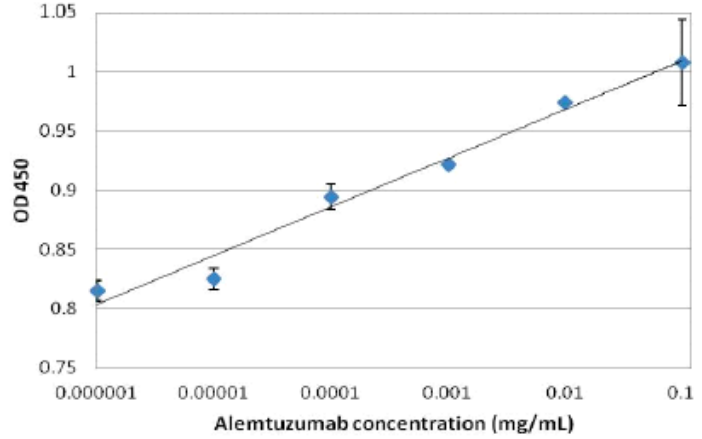
Definition of the Variables Affecting Efficacy of Immunodepletion Ex Vivo of Peripheral Blood Progenitor Cell Grafts by Alemtuzumab (Campath in the Bag)

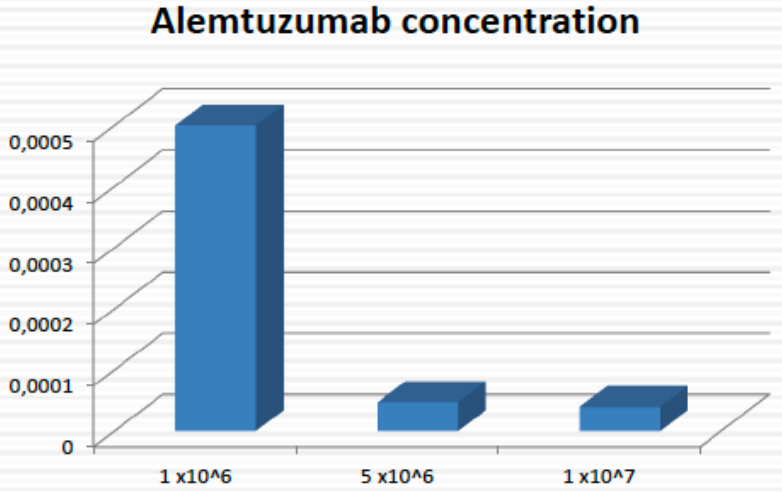
Nicolas Novitzky [1,2,3,*], Glenda Davison [1,2,4], Rygana Abdulla [1,2], Shaheen Mowla [1,2]

[1] Division of Haematology, University of Cape Town Leukaemia Unit, Cape Town, South Africa
[2] Department of Clinical Laboratory Sciences, Groote Schuur Hospital, Observatory, Cape Town, South Africa
[3] Department of Medicine, Groote Schuur Hospital, Observatory, Cape Town, South Africa
[4] Department of Biomedical Sciences, Faculty of Health and Wellness Sciences, Cape Peninsula University of Technology, Cape Town South Africa

DEFINITELY NEED COMPLEMENT / SERUM TO ACTIVATE CAMPATH







we were able to derive that the optimal cell kill in the graft without detectable free alemtuzumab in the supernatant can be achieved with **1 mg of antibody per 100 mL containing 10 X10^9 cells** and complement

IN SUMMARY – CURRENT TRANSPLANT STRATEGIES EMPLOYED

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PUBLIC SECTOR

- Lymphoid malignancies
  - TBI-FLU
  - MRD : no ATG
  - MUD : add ATG (3mg/kg x 3)
  - Campath in the bag – calculated
  - CSA from D-1
- Myeloid malignancies
  - BuMelFlu
  - MRD : no ATG
  - MUD: add ATG
  - Campath in the bag – calculated
  - CSA from D-1

PRIVATE SECTOR

- Lymphoid malignancies
  - TBI-FLU
  - MRD : no ATG
  - MUD : add ATG (1.5mg/kg x4)
  - Campath in the bag
    - MRD – 8mg
    - MUD – 12mg
  - CSA or Tacro from D-1
- Myeloid malignancies
  - BuMelFlu
  - MRD : no ATG
  - MUD: add ATG
  - Campath in the bag
    - MRD – 8mg
    - MUD – 12mg
  - CSA or Tacro from D-1

WHAT ABOUT HAPLO TRANSPLANTS IN SOUTH AFRICA?

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- IMPERATIVE AS
  - SA bone marrow registries not representative of our local population
  - We have a very ethnically diverse population
  - SA has the highest seroprevalence of HIV in the world (13.1%) which restrict our donor pool
  - MUD transplants (international donors) can be prohibitively expensive even for patients on a medical aid or insurance
  - Especially in time sensitive haematological malignancies

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Is Haploidentical Haematopoietic Cell Transplantation Using Post-Transplantation Cyclophosphamide (PTCY) Feasible In Sub-Saharan Africa?

Justin du Toit[1,3,*], Andrew Mcdonald[2], David Brittain[2], Michael Cass[2], Jackie Thomson[1], Jenna Oosthuisen[3], Cecile du Toit[3], Matthew Seftel[3,4], Vernon Louw[3], Estelle Verburgh[3]

[1]Wits Donald Gordon Cellular and Immunotherapy Centre, Johannesburg, South Africa

[2]ACT, Pretoria East Netcare Hospital, Pretoria, South Africa

[3]Devision of Clinical Haematology, Department of Medicine, Groote Schuur Hospital, University of Cape Town, Cape Town, South Africa

[4]Division of Haematology, Department of Medicine, University of British Columbia, Vancouver, Canada

Mixture of myeloablative and reduced intensity conditioning but using PTCY

Transplant Cell Ther. 2021 December ; 27(12): 1002.e1–1002.e8. doi:10.1016/j.jtct.2021.08.018.

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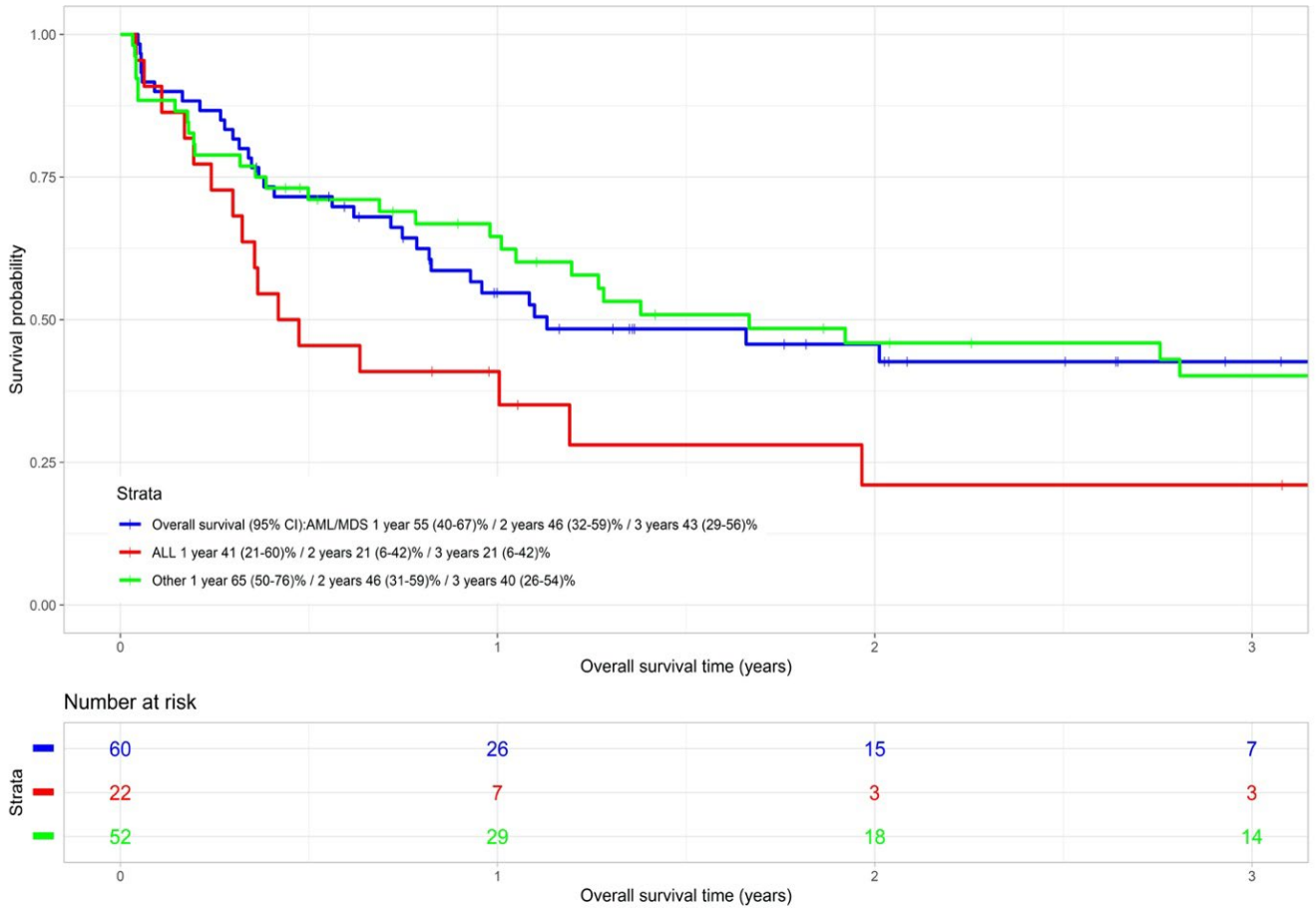
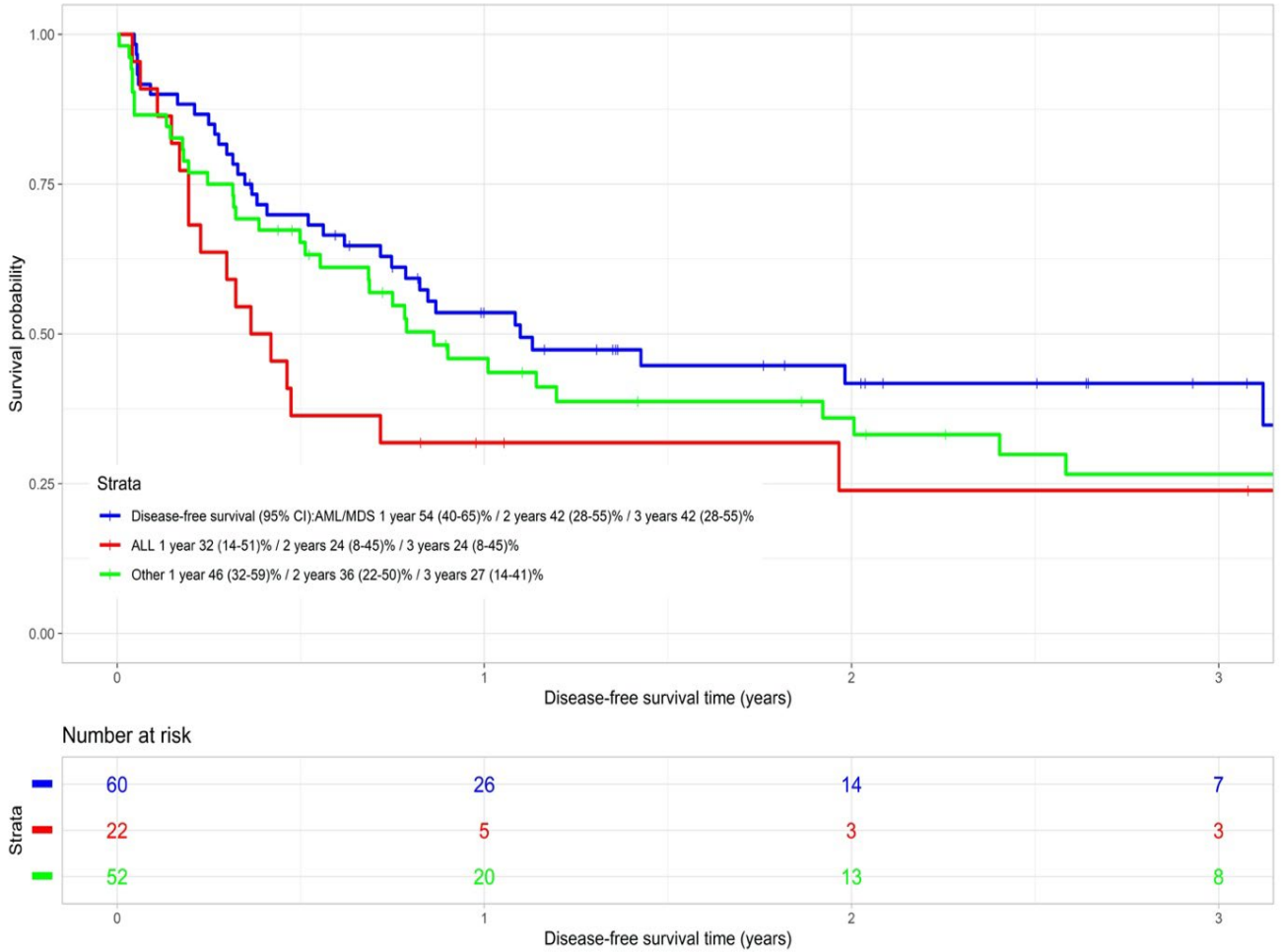
- Retrospectively analysis, 134 patients,haematological malignancies - received unmanipulated haploSCT with PTCY at two high volume SCT centers between 2014 - 2019.
- **Public & private collaboration (GSH & PEN)**
- We assessed
  - Overall survival (OS)
  - Disease free survival (DFS)
  - Non-relapse mortality (NRM)
  - Relapse incidence (RI)
  - Incidence of acute GVHD (aGVHD) – day 100

OVERALL SURVIVAL – DISEASE TYPE



OS	AML/MDS (95% CI)	ALL	OTHER
1 YR	55 (40-67)	41 (21-60)	65 (50-76)
2 YR	46 (32-59)	21 (6-42)	46 (31-59)
3 YR	43 (29-56)	21 (6-42)	40 (26-54)

DISEASE FREE SURVIVAL – DISEASE TYPE

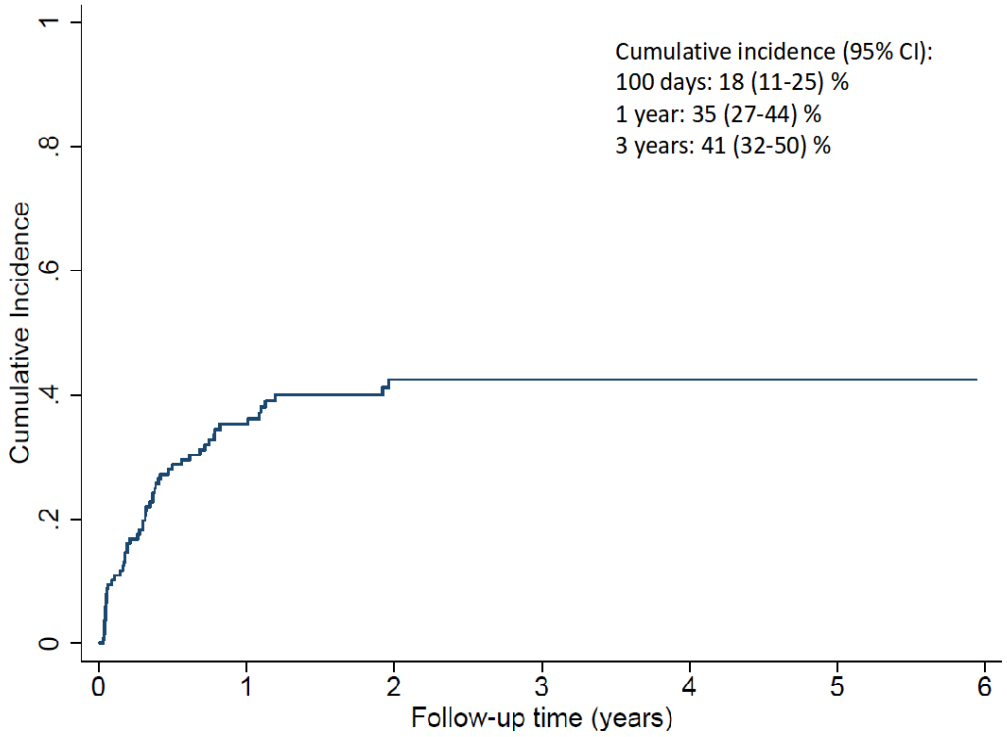


DFS	AML/MDS (95% CI)	ALL	OTHER
1 YR	54 (40-65)	32 (14-51)	46 (32-59)
2 YR	42 (28-55)	24 (8-45)	36 (22-50)
3 YR	42 (28-55)	24 (8-45)	27 (14-41)

ACUTE GVHD RATES

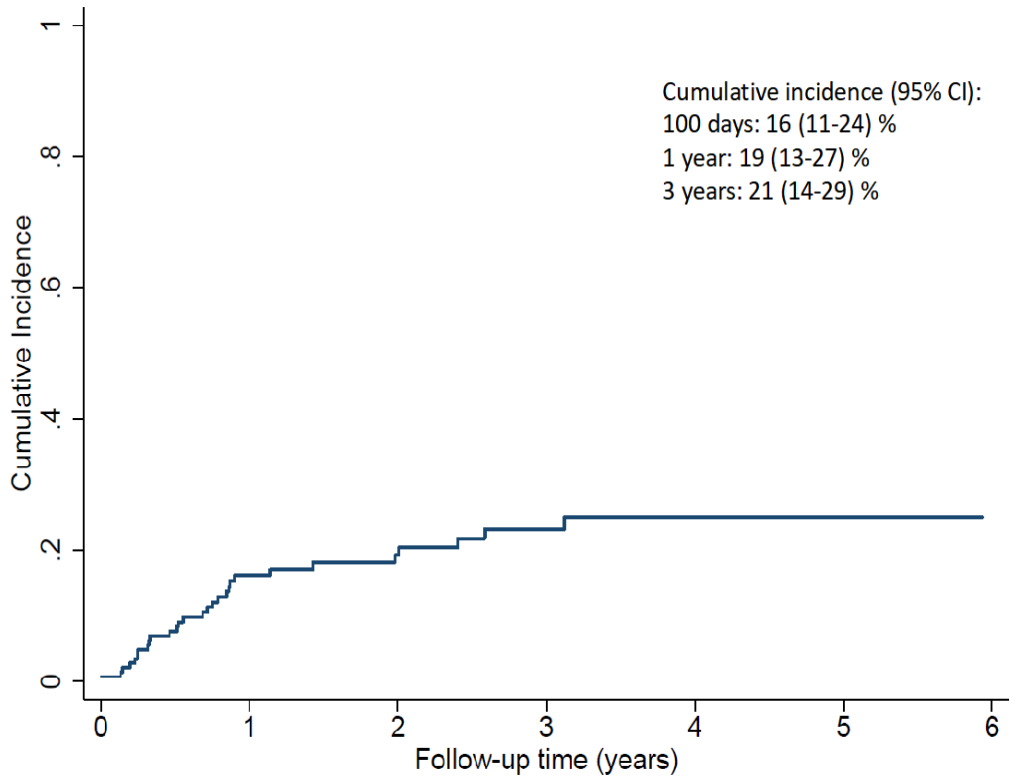
- Acute GVHD
  - Yes 45 (41.7 %)
  - No 63 (58.3 %)
- Acute GVHD grade
  - I = 17 (37.8%)
  - II = 19 (42.2%)
  - III = 6 (13.3%)
  - IV = 3 (6.7%)

CUMULATIVE INCIDENCE OF NON-RELAPSE MORTALITY



Characteristic	Value
Cause of death, n (%)	76 (100)
- HCT related cause*	53 (69.7)
- Relapse or progression	20 (26.3)
- Unknown	3 (3.9)
Contributary cause of death, n (%)	76
- Bacterial infection	31 (40.8)
- Graft failure/poor graft function	23 (30.3)
- Viral infection	22 (28.9)
- Fungal infection	20 (26.3)
- GVHD	19 (25.0)
- Multiple organ failure	13 (17.1)
- Pulmonary toxicity	5 (6.6)
- Renal failure	5 (6.6)
- Cardiac toxicity	3 (3.9)

CUMULATIVE INCIDENCE OF RELAPSE



UNIVARIATE & MULTIVARIATE REGRESSION ANALYSIS

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On univariate analysis: older recipient age (>56 years) was a risk factor for NRM.

Characteristic	Disease free survival			Relapse incidence		
	HR	95%CI	p-value	HR	95%CI	p-value
Donor age						
46 – 68 years	1.9	1.02-3.53	0.043	-	-	-
36 – 45 years	1.4	0.7-2.8	0.34	-	-	-
26 – 35 years	1.16	0.6-2.28	0.66	-	-	-
9 – 25 years	1.0	reference	-	-	-	-
Diagnostic group						
Other*	-	-	-	2.62	1.12-6.15	0.027
ALL group	-	-	-	1.51	0.38-5.96	0.56
AML/MDS group	-	-	-	1.0	reference	-
Stem cell source						
PBSC	-	-	-	0.43	0.19-0.95	0.038
BM	-	-	-	1.0	reference	-
Donor relation						
Offspring	-	-	-	0.25	0.09-0.67	0.006
Sibling	-	-	-	0.39	1.15-1.01	0.053
Parent	-	-	-	1.0	reference	-

DISCUSSION

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- AML/MDS subgroup OS approximates other reference centres
- However, the ALL group seems inferior versus other publications
- Multivariate regression analysis:
  - Older donor age (46-68y vs. 9-25y) was significantly associated with inferior DFS - conflicting evidence on this topic
  - Lower RI with offspring donors - similar observations Solomon & McCurdy et al
  - Lower RI with use PBSC versus, 2 meta-analyses (Durer & Yu et al) : higher aGVHD no impact OS and RI
- Our 100-day NRM is on par but 3-year NRM inferior to other publications
  On univariate analysis older recipient age = risk factor for inferior NRM
- High rate of graft failure/dysfunction : 17.2% entire cohort

ADVANTAGES OF OUR STUDY

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- First collaboration private & public transplant centres. Stimulate ongoing research & collaboration!
- This data serves now as our comparator - improve outcomes & quality of health care for our patients
- Haplo SCT is a valid option for patients HR haematological malignancies in SA
  - as compared to unrelated donor transplantation, is consistent with the imperative to provide *affordable and equitable access* to stem cell transplantation for all patients in South Africa irrespective of socio-economic status

CONCLUSION OF THIS STUDY

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We conclude that our data confirms the feasibility of unmanipulated haploHCT in SA and suggests that utilizing **younger parental or offspring donors** are valid options for adults with acute leukaemia and MDS lacking a related or unrelated donor

WE CURRENTLY FACING A CHALLENGE – ACCESS CAMPATH

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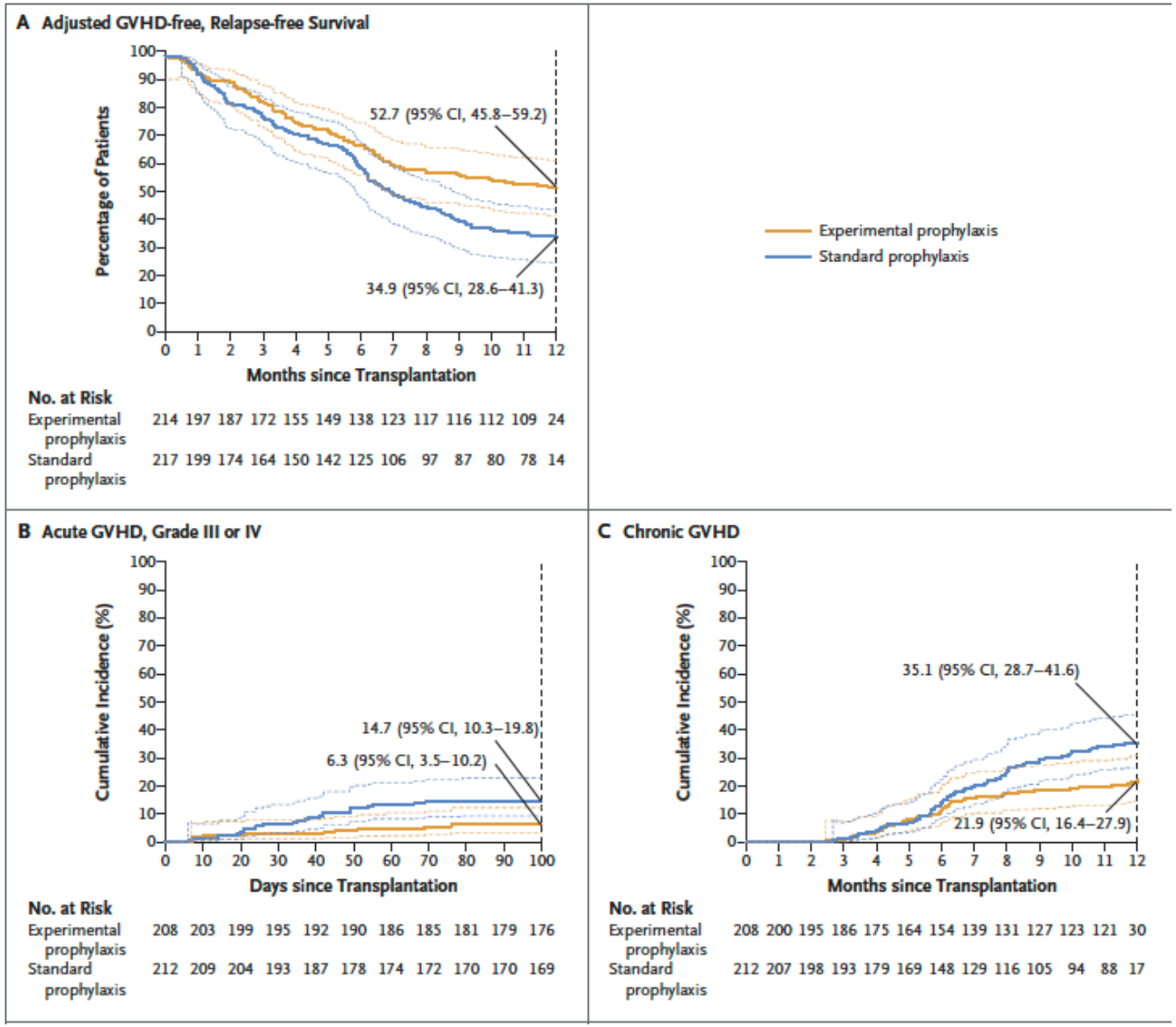
- Campath has always been accessed via a compassionate use program (Sanofi-Genzyme) for public and private patients
- Campath was not registered in SA, but applied for through section 21 application (SAHPRA)
- Lemtrada has now been registered and therefore we cannot apply a section 21 application anymore, RESTRICTING ITS COMPASSIONATE USE
- Concern currently is access to public and some private patients

IS PTCY THE SOLUTION FOR SOUTH AFRICA ?

WDG CELLULAR + IMMUNOTHERAPY CENTRE. PATIENT CENTRIC CELLULAR THERAPIES

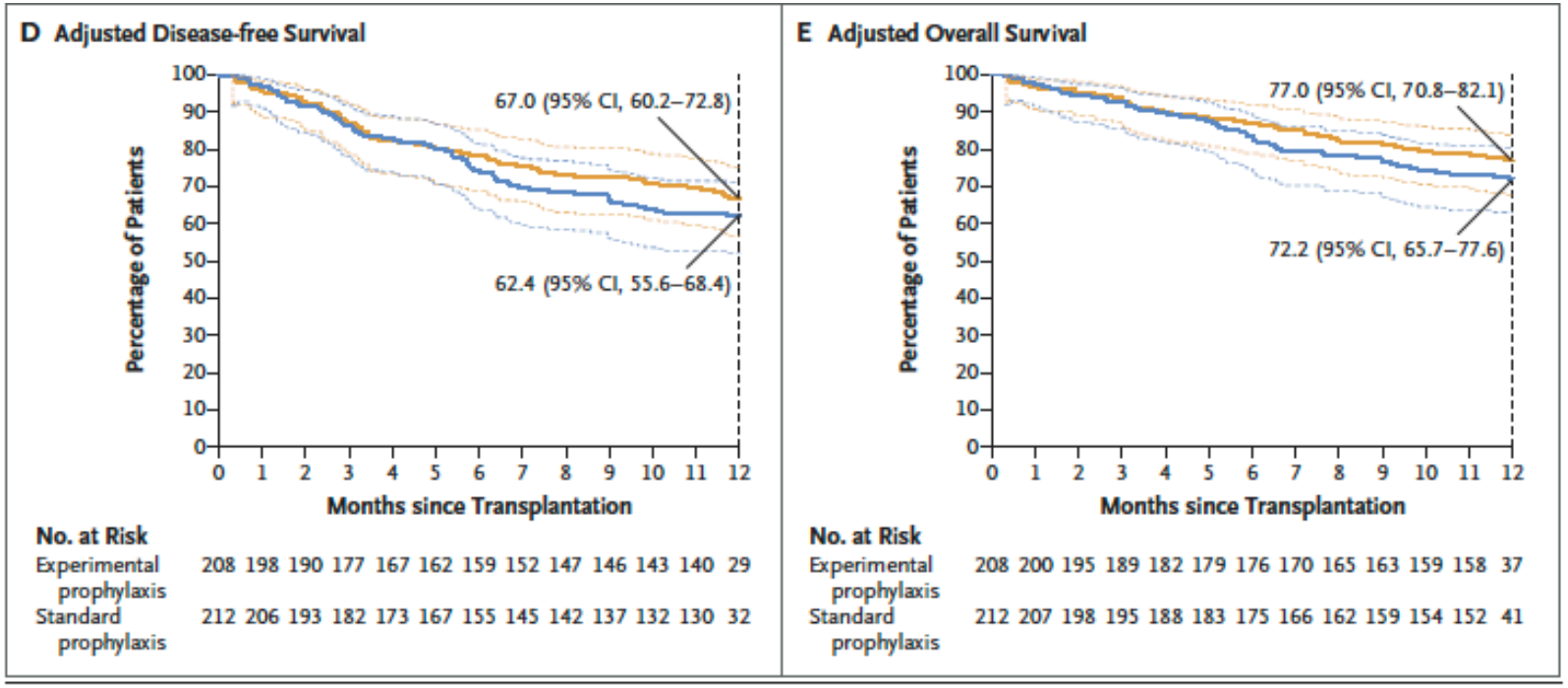


Post-Transplantation Cyclophosphamide-Based Graft-versus-Host Disease Prophylaxis

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*

- RIC
- Phase III RCT
- MRD/MUD/MMUD
- Compared
  - PTCY + Tacro + MMF
  - Tacro + MTX

AT LEAST PTCY IS ACCESSIBLE AND CHEAP – KEEPING PUBLIC SECTOR IN MIND



- Among patients undergoing allo HLA-matched SCT with RIC
- GVHD-free, relapse-free survival at 1 year was significantly more common among PTCY–tacrolimus–MMF vs tacrolimus–methotrexate

THANK YOU! ANY QUESTIONS?

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WDG
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