

Convegno Educazionale GITMO

LE TERAPIE CELLULARI IN EMATOLOGIA TRA PASSATO, PRESENTE E FUTURO

Brescia, 28-29 novembre 2025

Centro Paolo VI

LA RICADUTA POST TRAPIANTO TERAPIA PRE-EMPTIVE

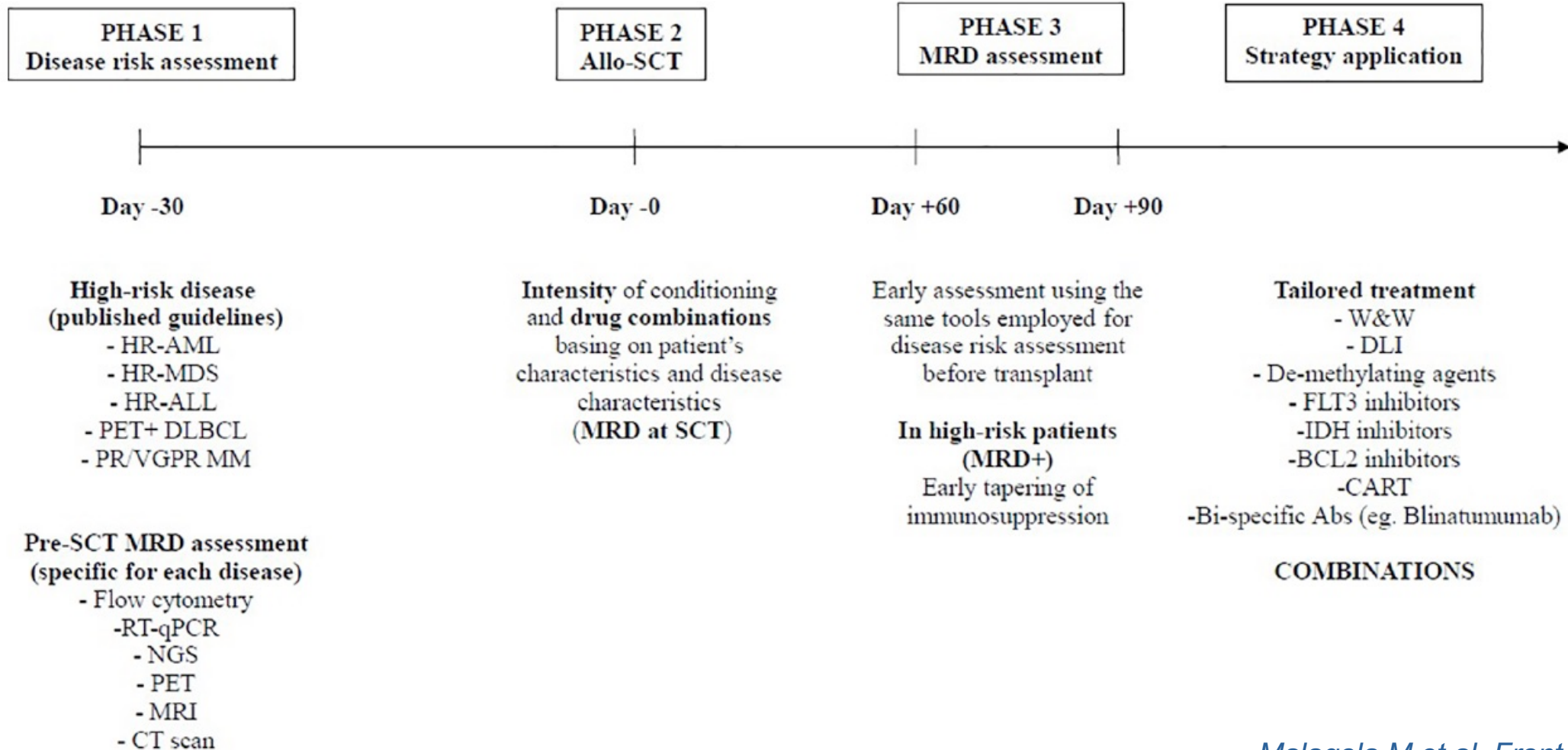
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Disclosures of MALAGOLA MICHELE

Company name	Research support	Employee	Consultant	Stockholder	Speakers bureau	Advisory board	Other
GRIFOLS						X	
TAKEDA						X	
MSD						X	
MEDAC						X	





Malagola M et al, Front Oncol 2022

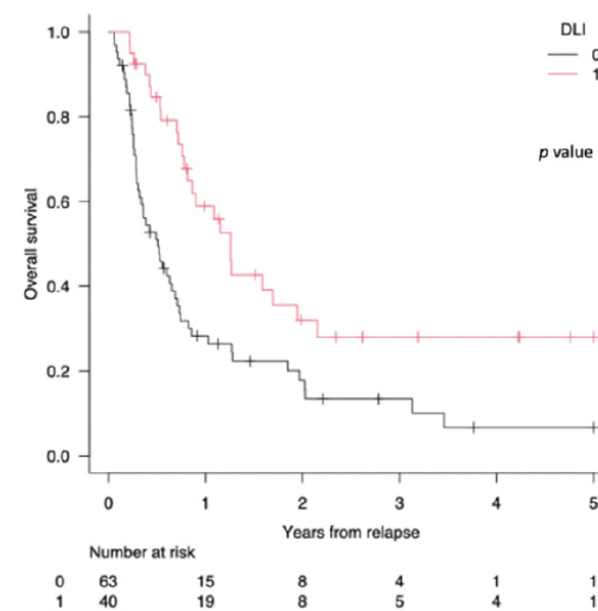
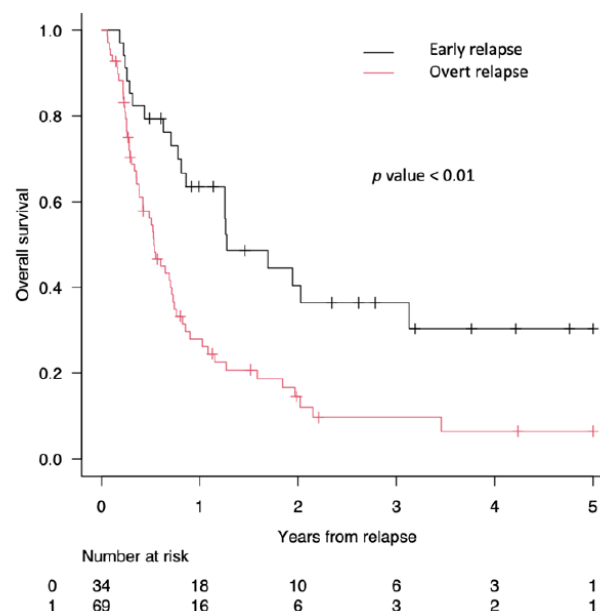


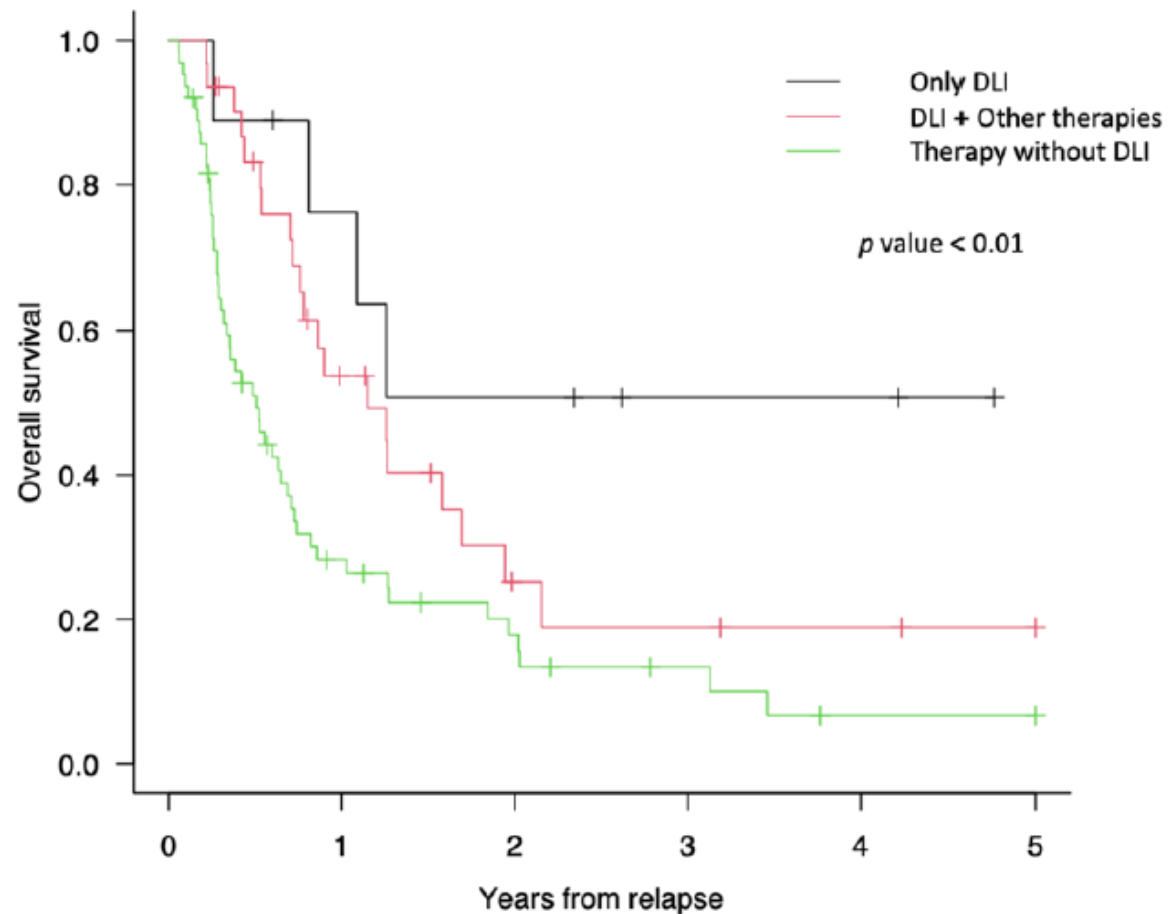
Article

Donor Lymphocyte Infusion in the Treatment of Post-Transplant Relapse of Acute Myeloid Leukemias and Myelodysplastic Syndromes Significantly Improves Overall Survival: A French–Italian Experience of 134 Patients

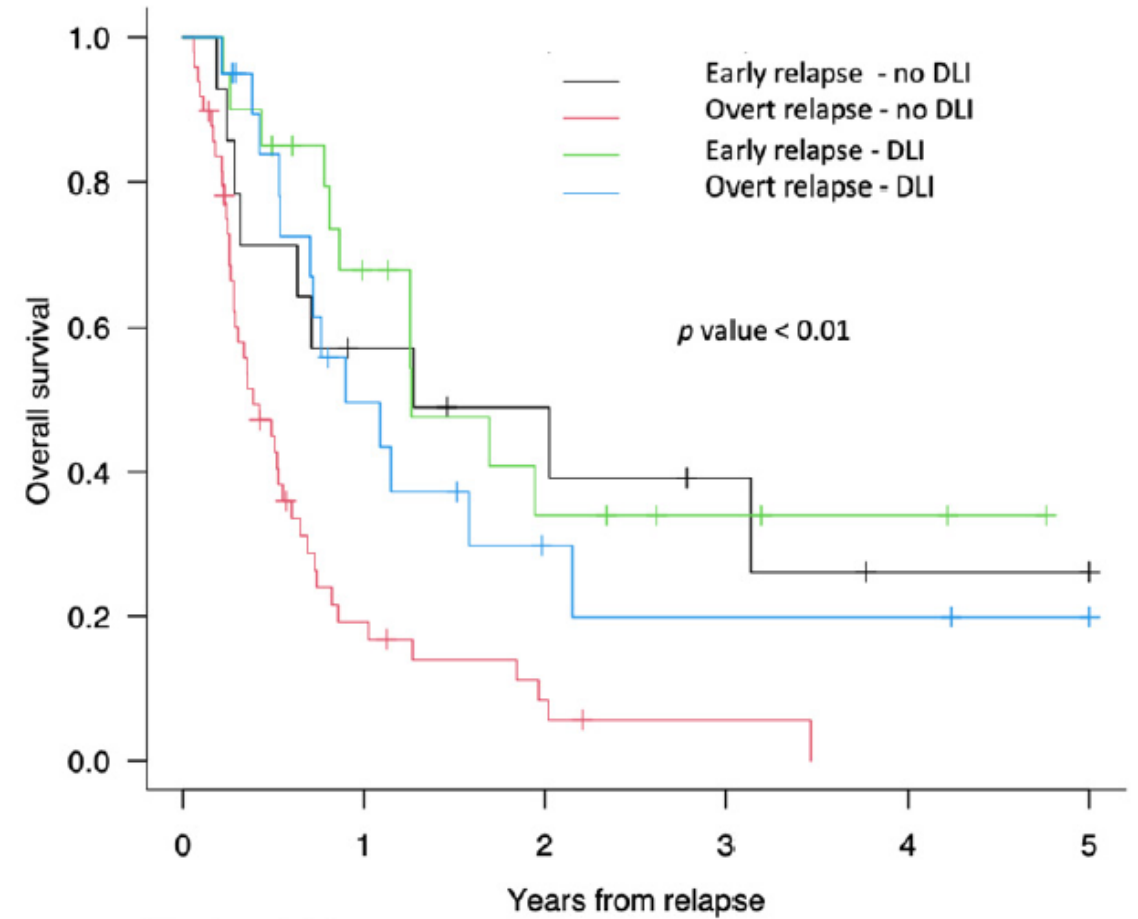
Eugenia Accorsi Buttini ^{1,*}, Cristina Doran ², Michele Malagola ¹, Vera Radici ¹, Marco Galli ¹, Vicky Rubini ¹, Alessandro Leoni ³, Mirko Farina ¹, Nicola Polverelli ⁴, Federica Re ³, Simona Bernardi ^{1,3}, Mohamad Mohty ², Domenico Russo ^{1,†} and Eolia Brissot ^{2,†}

2024





Number at risk						
0	9	6	4	2	2	0
1	31	13	4	3	2	1
2	63	15	8	4	1	1



Number at risk						
0:0	14	7	5	3	1	1
1:0	49	8	3	1	0	0
0:1	20	11	5	3	2	0
1:1	20	8	3	2	2	1

Accorsi Buttini, E,.....Malagola M et al, Cancers 2024

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Brescia, 28-29 novembre 2025

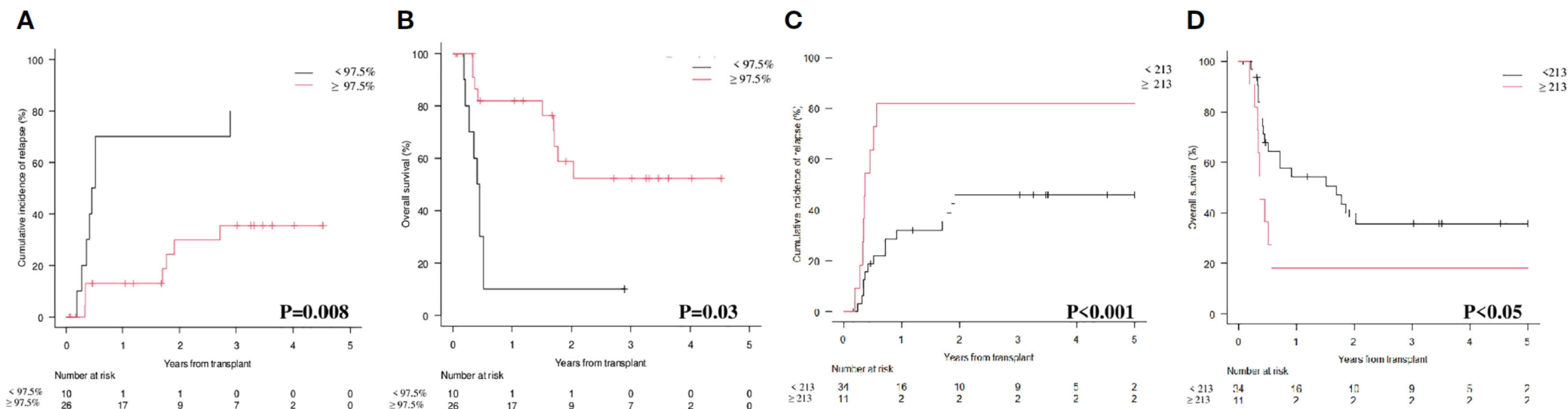


Bone marrow CD34+ molecular chimerism as an early predictor of relapse after allogeneic stem cell transplantation in patients with acute myeloid leukemia

Michele Malagola^{1*†}, Nicola Polverelli^{1†}, Alessandra Beghin², Federica Bolda², Marta Comini², Mirko Farina¹, Enrico Morello¹, Vera Radici¹, Eugenia Accorsi Buttini¹, Simona Bernardi^{1,3}, Federica Re^{1,3}, Alessandro Leoni^{1,3}, Davide Bonometti⁴, Duilio Brugnani⁵, Arnalda Lanfranchi^{2†} and Domenico Russo^{1†}

frontiers | Frontiers in Oncology

2023

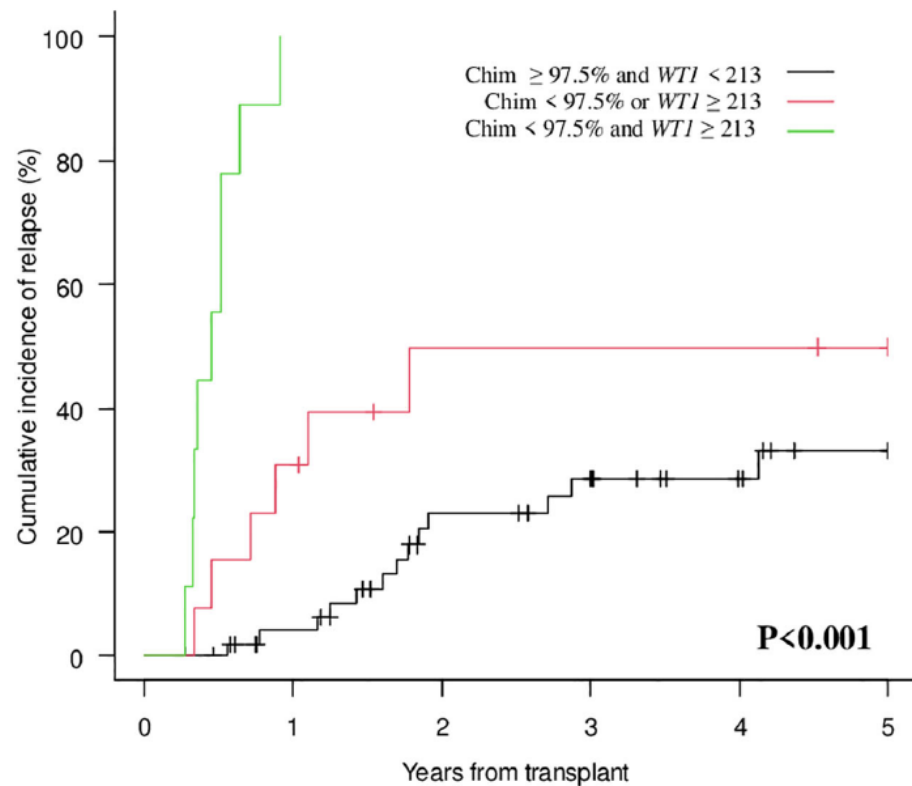


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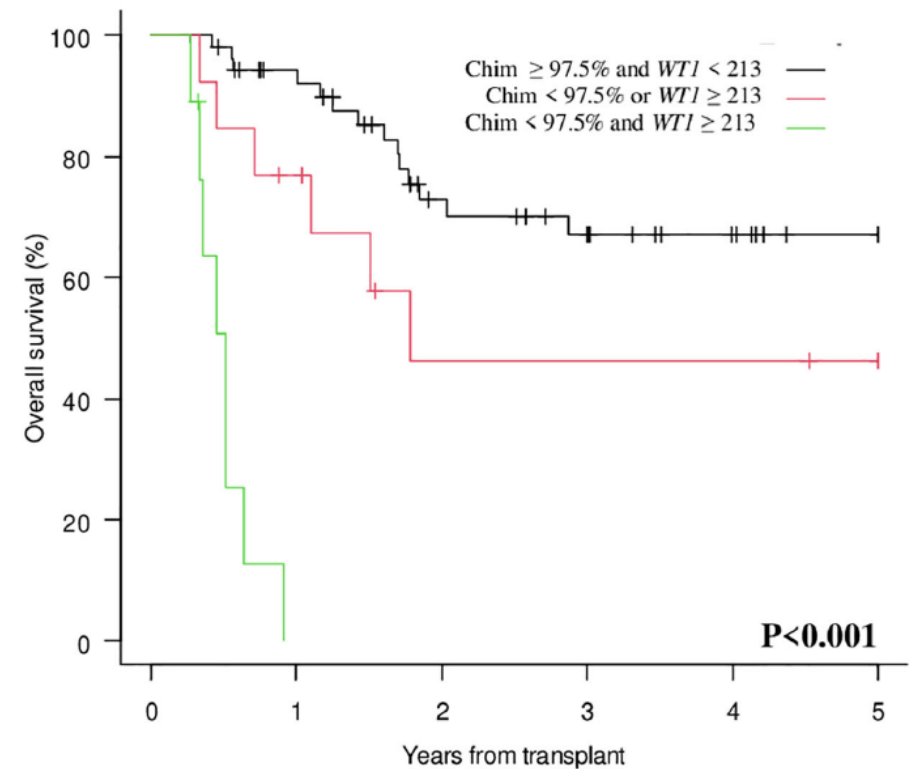


A



	Number at risk					
	0	1	2	3	4	5
Chim $\geq 97.5\%$ and $WT1 < 213$	53	43	27	22	14	9
Chim $< 97.5\%$ or $WT1 \geq 213$	13	9	4	4	4	1
Chim $< 97.5\%$ and $WT1 \geq 213$	9	0	0	0	0	0

B



	Number at risk					
	0	1	2	3	4	5
Chim $\geq 97.5\%$ and $WT1 < 213$	53	43	27	22	14	9
Chim $< 97.5\%$ or $WT1 \geq 213$	13	9	4	4	4	1
Chim $< 97.5\%$ and $WT1 \geq 213$	9	0	0	0	0	0

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LE TERAPIE CELLULARI IN EMATOLOGIA TRA PASSATO, PRESENTE E FUTURO

Brescia, 28-29 novembre 2025





2025

CORRESPONDENCE

Outcome of Patients With Acute Myeloid Leukemias or Myelodysplastic Syndromes After Relapsing From Allogeneic Stem Cell Transplantation: The GITMO AML/MDS-Relapse Registry Study

Malagola Michele^{1,2}  | Castagna Luca³  | Matranga Domenica⁴  | Radici Vera^{1,2} | Farina Mirko^{1,2} | Galli Marco^{1,2} | Accorsi Buttini Eugenia⁵ | Rubini Vicky⁶ | Alati Caterina⁷ | Bassi Simona⁸ | Biffi Alessandra⁹ | Borghero Carlo¹⁰ | Busca Alessandro¹¹ | Nozzoli Chiara¹² | Carella Angelo Michele¹³ | Cavattoni Irene¹⁴ | Cerretti Raffaella¹⁵ | Chiusolo Patrizia¹⁶  | Cimminiello Michele¹⁷ | Cuoghi Angela¹⁸ | De Gobbi Marco^{19,20}  | Vincenzo Federico²¹ | Galieni Piero²² | Iori Anna Paola²³ | Olivieri Attilio²⁴ | Parma Matteo²⁵ | Patriarca Francesca²⁶ | Pavone Vincenzo²⁷ | Picardi Alessandra²⁸ | Piras Eugenia²⁹ | Polverelli Nicola³⁰  | Prezioso Lucia³¹ | Rambaldi Benedetta³² | Scalisi Elvira³³ | Selleri Carmine³⁴ | Skert Cristina³⁵ | Spina Alessandro³⁶ | Tecchio Cristina³⁷ | Oldani Elena³² | Eliana Degrandi³⁸ | Domenico Russo^{1,2} | Martino Massimo⁷ 



TABLE 1 | Clinical and transplant characteristics of the 859 AML/MDS patients relapsing after allo-SCT included in the study.

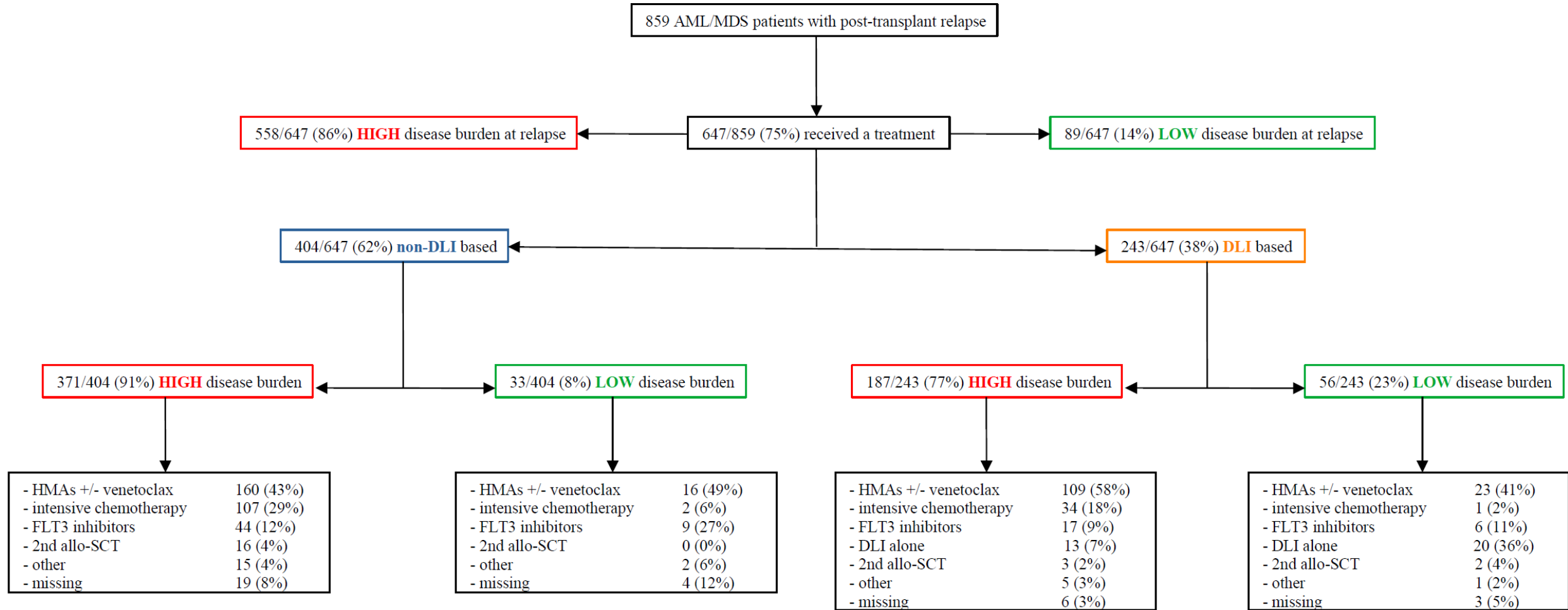
<i>n</i> = 859	
Age at diagnosis (years)	
Mean (SD)/median (Min, Max)	58.5 (12.1)/61.0 [23.0–80.0]
Age at SCT (years)	
Mean (SD)/median [Min, Max]	52.9 (12.2)/54.7 [18.7–74.8]
Diagnosis at SCT	
AML/MDS	768 (90%)/91 (10%)
Disease status at SCT	
No-CR/CR	352 (41%)/507 (59%)
Lines of therapy before SCT	
> 1/1	419 (49%)/415 (48%)
Missing	25 (3%)
Donor type	
Sibling	242 (28%)
MUD/MMUD	416 (48%)
Haploidentical	197 (23%)
Missing	4 (1%)
SCs source	
BM	203 (24%)
PBSC	646 (75%)
UCB	10 (1%)
MAC regimen	
No/Yes	248 (29%)/611 (71%)
GVHD prophylaxis	
ATG/ATLG	600 (70%)
PTCy	188 (22%)

aGVHD	
No/Yes	508 (59%)/210 (24%)
Grade II/IV aGVHD	141 (17%)
cGVHD	
No	680 (79%)
Yes	110 (13%)
Extensive cGVHD	69 (8%)
Time SCT-relapse (months)	
Mean (SD)/Median [Q1, Q3]	8.85 (10.1)/5.49 [3.0–11.1]
Survivors follow-up time (months)	
Mean (SD)/Median [Q1, Q3]	47.0 (24.5)/41.8 [29.2–65.57]



FLOW CHART

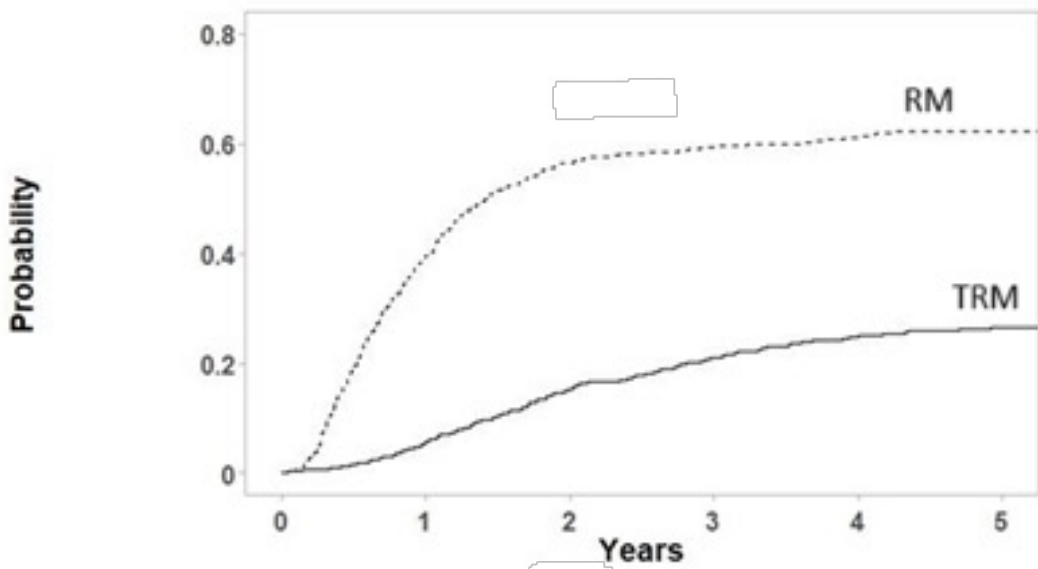
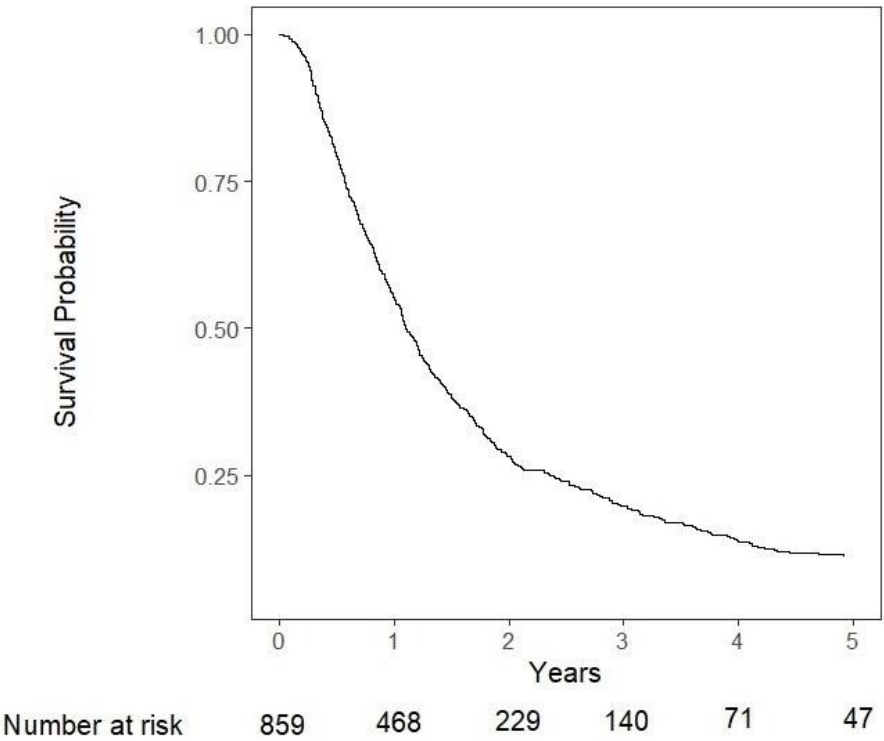
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308 pts received post-relapse tx with HMAs +/- VEN



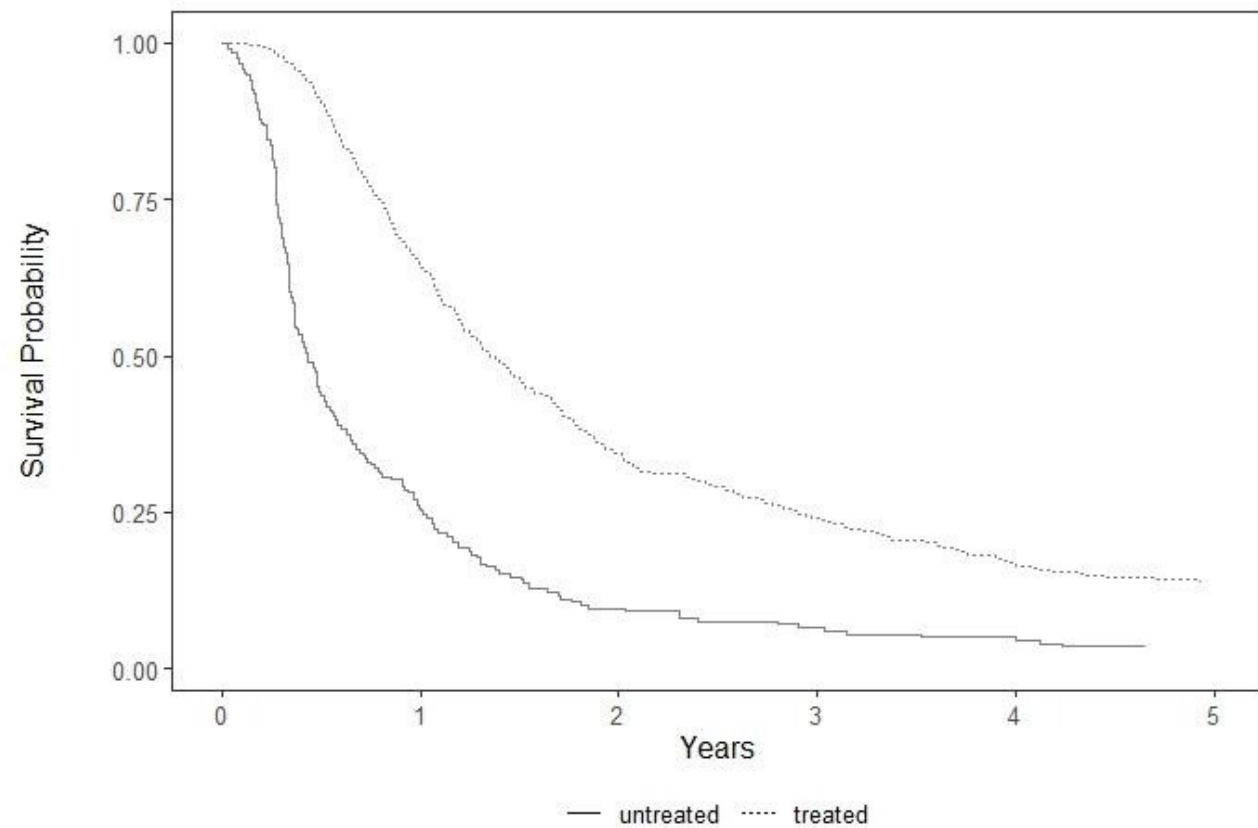
OS



N patients at risk	859	468	229	140	71	48
NRM	0	49	128	172	197	204
RM	0	338	480	501	514	518



OS



	Number at Risk					
untreated	212	52	19	13	10	6
treated	647	416	210	127	61	41



SUBANALYSIS GITMO AML/MDS relapse

HIGH vs LOW

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Brescia, 28-29 novembre 2025



PATIENTS' AND TRANSPLANT CHARACTERISTICS

HIGH disease burden



Hematological relapse

LOW disease burden



MRD+ and/or molecular mixed chimerism

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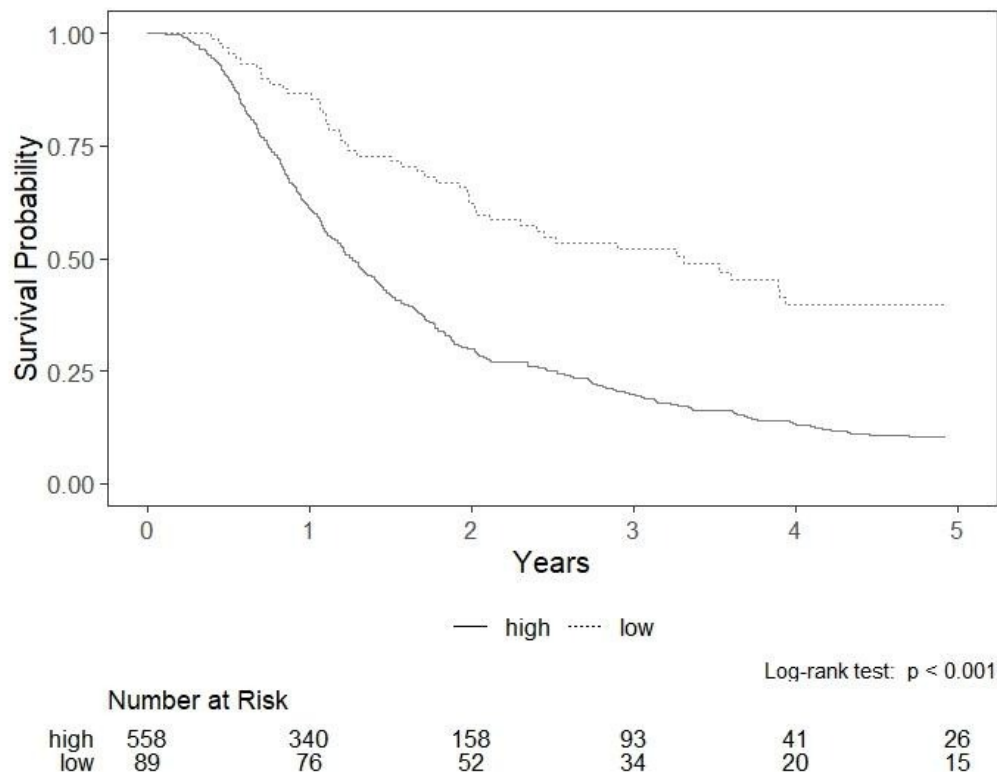
LE TERAPIE CELLULARI IN EMATOLOGIA TRA PASSATO, PRESE
Brescia, 28-29 novembre 2025

	Relapse setting		Total	P-Value
	HIGH	LOW		
	n = 757	n = 102	n = 859	
Age at diagnosis (years) *				
Mean (SD)	58.6 (12.0)	57.9 (13.3)	58.5 (12.1)	0,86
Median [Min, Max]	61.0 [23.0-80.0]	61.0 [25.0-77.0]	61.0 [23.0-80.0]	
Age at SCT (years) *				
Mean (SD)	53.0 (12.0)	52.4 (13.1)	52.9 (12.2)	0,889
Median [Min, Max]	54.7 [18.7-74.8]	54.5 [19.5- 69.7]	54.7 [18.7-74.8]	
Diagnosis at SCT *				
AML	675 (89.%)	93 (91%)	768 (90%)	0,826
MDS	82 (11%)	9 (9%)	91 (10%)	
Disease status at SCT *				
No-CR	317 (42%)	35 (34%)	352 (41%)	0,346
CR	440 (58%)	67 (66%)	507 (59%)	
Lines of therapy before SCT *				
>1	377 (50%)	42 (41%)	419 (49%)	0,214
1	357 (47%)	58 (57%)	415 (48%)	
Missing	23 (3%)	2 (2%)	25 (3%)	
Donor type *				
Sibling	220 (29%)	22 (22%)	242 (28%)	0,622
MUD/MMUD	361 (48%)	55 (54%)	416 (48%)	
Haploidentical	172 (22%)	25 (24%)	197 (23%)	
Missing	4 (1%)	0 (0%)	4 (1%)	
SCs source *				
BM	175 (23%)	28 (27%)	203 (24%)	0,42
PBSC	572 (76%)	74 (73%)	646 (75%)	
UCB	10 (1%)	0 (0%)	10 (1%)	
MAC regimen *				
No	217 (29%)	31 (30%)	248 (29%)	0,937
Yes	540 (71%)	71 (70%)	611 (71%)	
aGVHD *				
No	453 (60%)	55 (54%)	508 (59%)	0,836
Yes	183 (24%)	27 (26%)	210 (24%)	
Grade II/IV aGVHD	121 (16%)	20 (20%)	141 (17%)	
cGVHD *				
No	610 (81%)	70 (69%)	680 (79%)	0,0521
Yes	93 (12%)	17 (17%)	110 (13%)	
Extensive cGVHD	54 (7%)	15 (15%)	69 (8%)	
Time SCT-relapse (months) #				
Mean (SD)	8.63 (9.74)	10.5 (12.2)	8.85 (10.1)	0,085
Median [Q1,Q3]	5.26 [3.0-11.0]	5.97 [3.4-11.8]	5.49 [3.0-11.1]	
Survivors follow-up time (months) #				
Mean (SD)	44.6 (24.1)	51.0 (24.9)	47.0 (24.5)	<0.001
Median [Q1,Q3]	39.9 [27.5-58.0]	49.4 [30.5-69.7]	41.8 [29.2-65.57]	

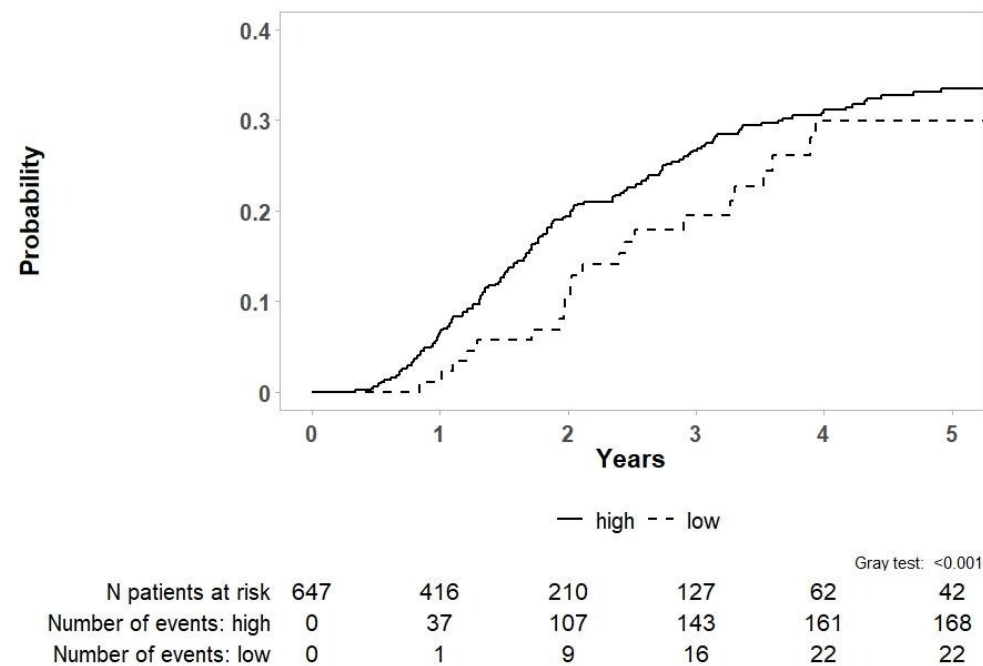


SUBANALYSIS - HIGH vs LOW (n=647 treated pts)

OS – 647 Treated PTS



TRM – 647 treated PTS

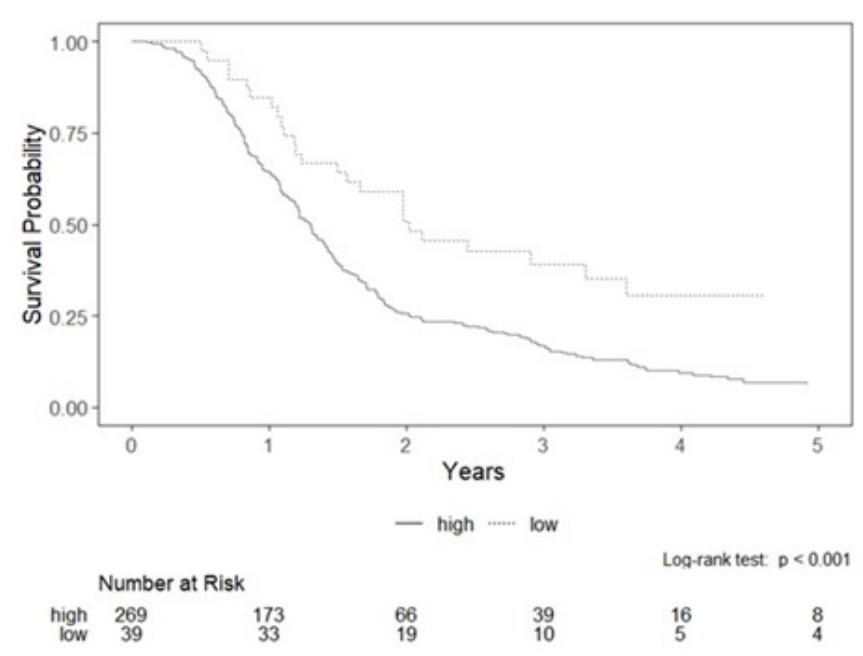


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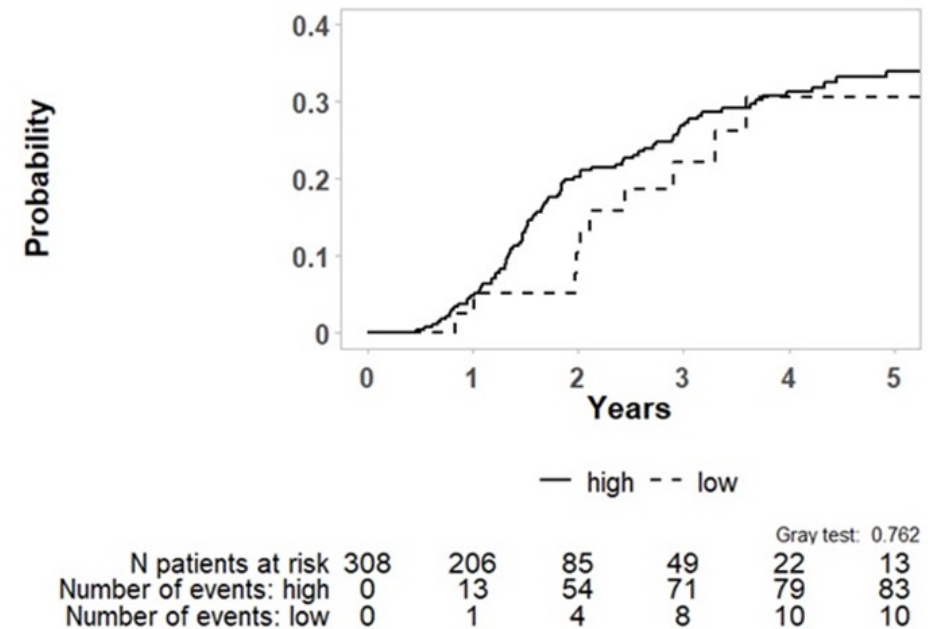


SUBANALYSIS - HIGH vs LOW (n=308 HMA +/- VEN)

OS – 308 HMAs +/- Ven



TRM – 308 HMAs +/- Ven

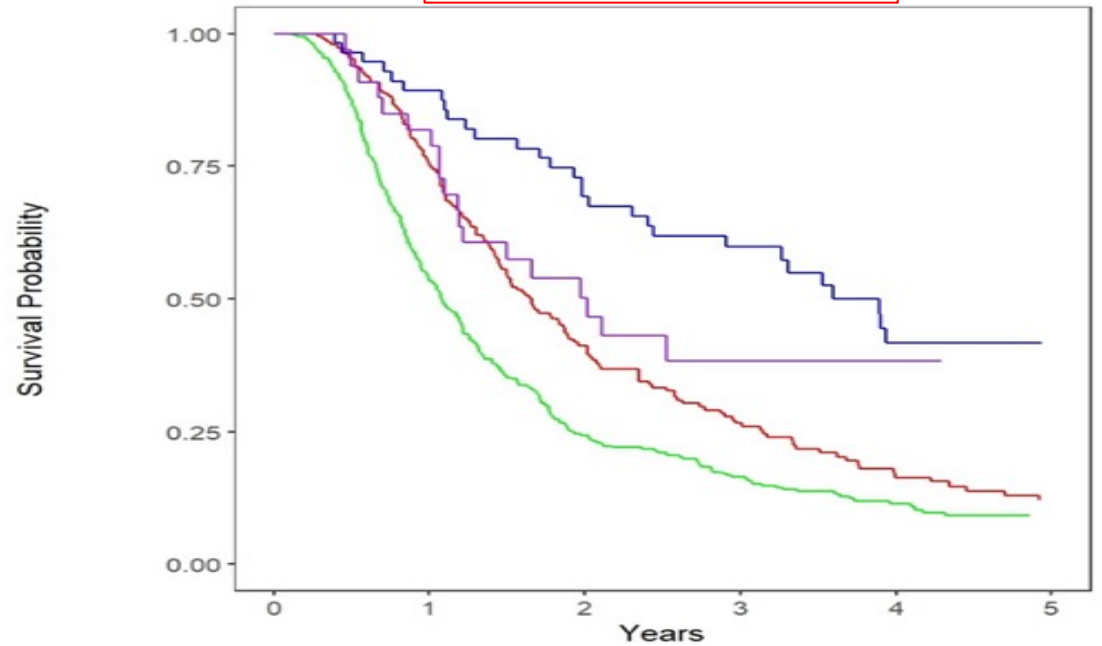


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SUBANALYSIS - HIGH vs LOW / DLI yes vs DLI no (n=647)

OS – 647 Treated PTS



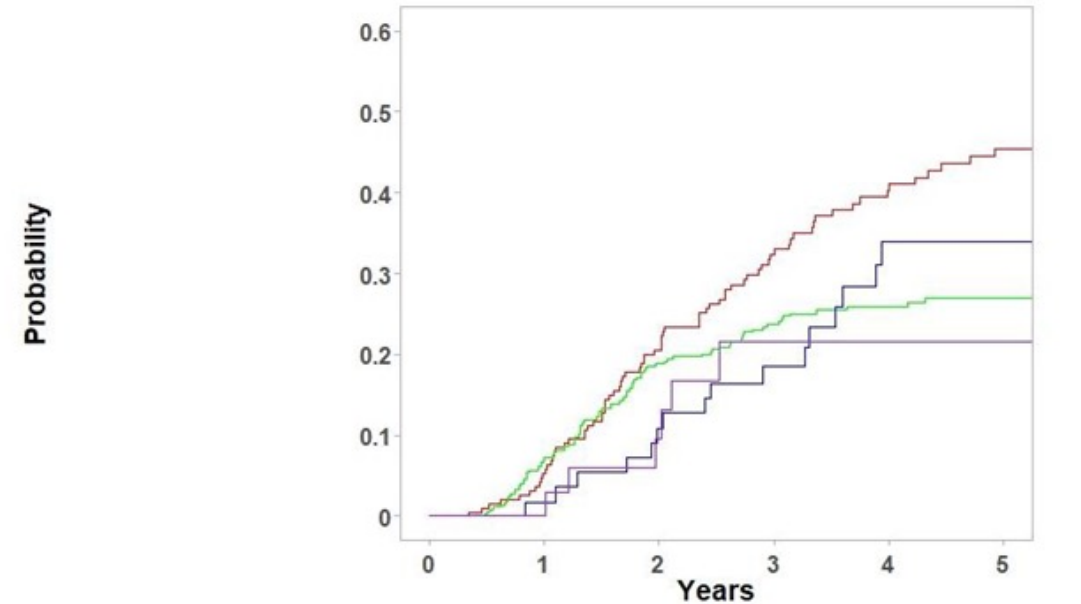
— high & DLI — high & no DLI — low & DLI — low & no DLI

Fleming-Harrington test: $p < 0.001$

Number at Risk

high & DLI	187	142	74	42	20	13
high & no DLI	371	198	84	51	21	13
low & DLI	56	49	38	27	14	10
low & no DLI	33	27	14	7	6	5

TRM – 647 treated PTS



— high & DLI — high & no DLI — low & DLI — low & no DLI

Gray test: <0.001

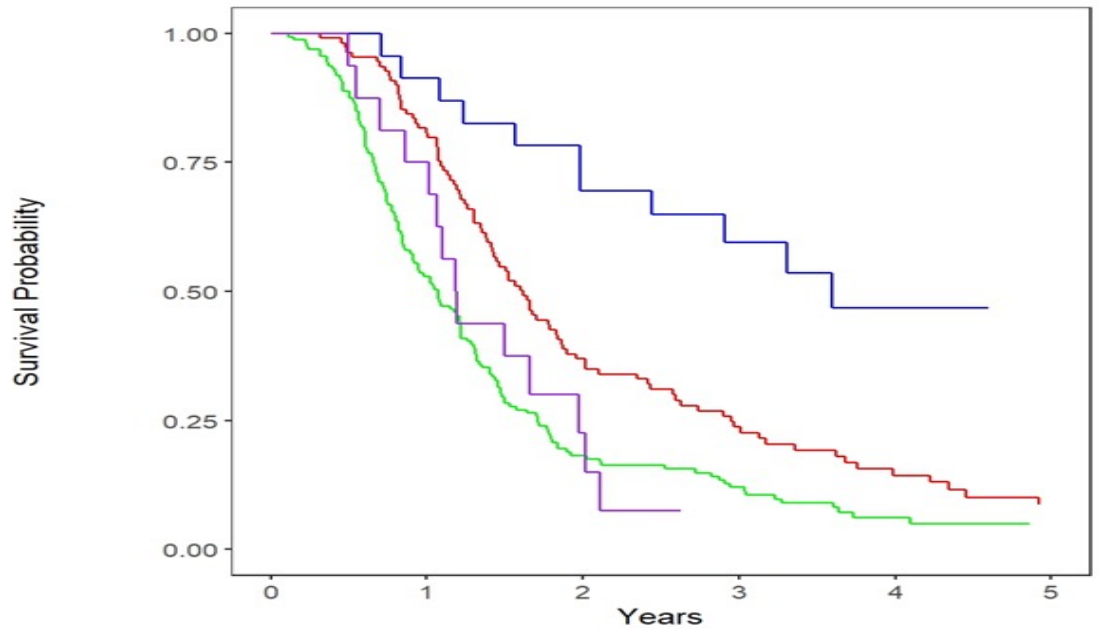
N patients at risk	647	416	210	127	62	42
Number of events: high & DLI	0	10	38	58	70	75
Number of events: high & no DLI	0	27	69	85	91	93
Number of events: low & DLI	0	1	6	10	16	16
Number of events: low & no DLI	0	0	3	6	6	6

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SUBANALYSIS - HIGH vs LOW / DLI yes vs DLI no (n=308 HMA +/- Ven)

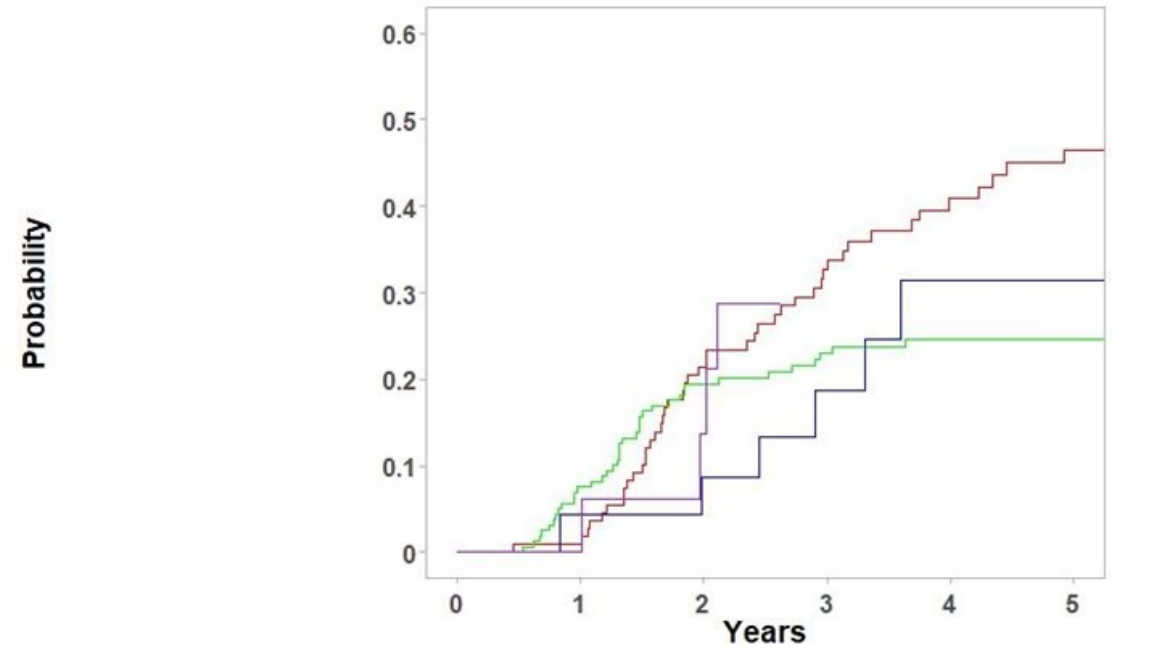
OS – 308 HMAs +/- Ven



Number at Risk

high & DLI	109	89	39	22	11	6
high & no DLI	160	84	27	17	5	2
low & DLI	23	21	16	10	5	4
low & no DLI	16	12	3	0	0	0

TRM – 308 HMAs +/- Ven



N patients at risk	308	206	85	49	22	13
Number of events: high & DLI	0	1	23	35	41	45
Number of events: high & no DLI	0	12	31	36	38	38
Number of events: low & DLI	0	1	2	4	6	6
Number of events: low & no DLI	0	0	2	4	4	4

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Univariable and Multivariable analysis on OS (HMAs +/- Ven)

Variables	Unit of measure / Category	Mean(SD) or n (%)	HR (univariable)			HR (multivariable)		
			HR	95%CI	p-value	HR	95%CI	p-value
Age at the baseline	Years	53.6 (11.7)	1.01	0.99-1.00	p=0.939			
Relapse time*	<12 months	228 (74.0)	0.06	0.03-0.13	p<0.001	0.05	0.02-0.10	p<0.001
	≥ 12 months	80 (26.0)						
Relapse disease burden	HIGH	269 (87.3)	0.49	0.33-0.74	p<0.001	0.44	0.29-0.67	p<0.001
	LOW	39 (12.7)						
Diagnosis at SCT	AML	277 (89.9)	0.9	0.60-1.34	p=0.596			
	MDS	31 (10.1)						
Disease status at SCT *	No-CR	130 (42.2)	0.57	0.44-0.73	p<0.001	0.49	0.38-0.64	p<0.001
	CR	178 (57.8)						
Lines therapy	>1	158 (51.3)	0.8	0.63-1.02	p=0.074			
	1	150 (48.7)						
Donor (vs Sibling) *	Sibling	80 (26.1)	0.81	0.61-1.09	p=0.173			
	MUD/MMUD/U	158 (51.5)						
	Haploidentical	69 (22.5)						
Stem Cells' source (vs BM)	BM	65 (21.1)	1.17	0.87-1.58	p=0.298			
	PBSC	241 (78.2)						
	UCB	2 (0.6)						
Myeloablative conditioning	NO	91 (29.5)	1.20	0.92-1.57	p=0.178			
	YES	217 (70.5)						
aGVHD (YES vs NO)	NO	185 (60.1)	1.1	0.83-1.47	p=0.505			
	YES	73 (23.7)						
	Grade II/IV	50 (16.2)						
GVHD post DLI	NO	279 (91.8)	0.49	0.30-0.78	p=0.003	0.59	0.35-0.98	p=0.041
	YES	25 (8.2)						
Post relapse first-line DLI based therapy *	NO	176 (57.1)	0.44	0.33-0.57	p<0.001	0.43	0.32-0.59	p<0.001
	YES	132 (42.9)						

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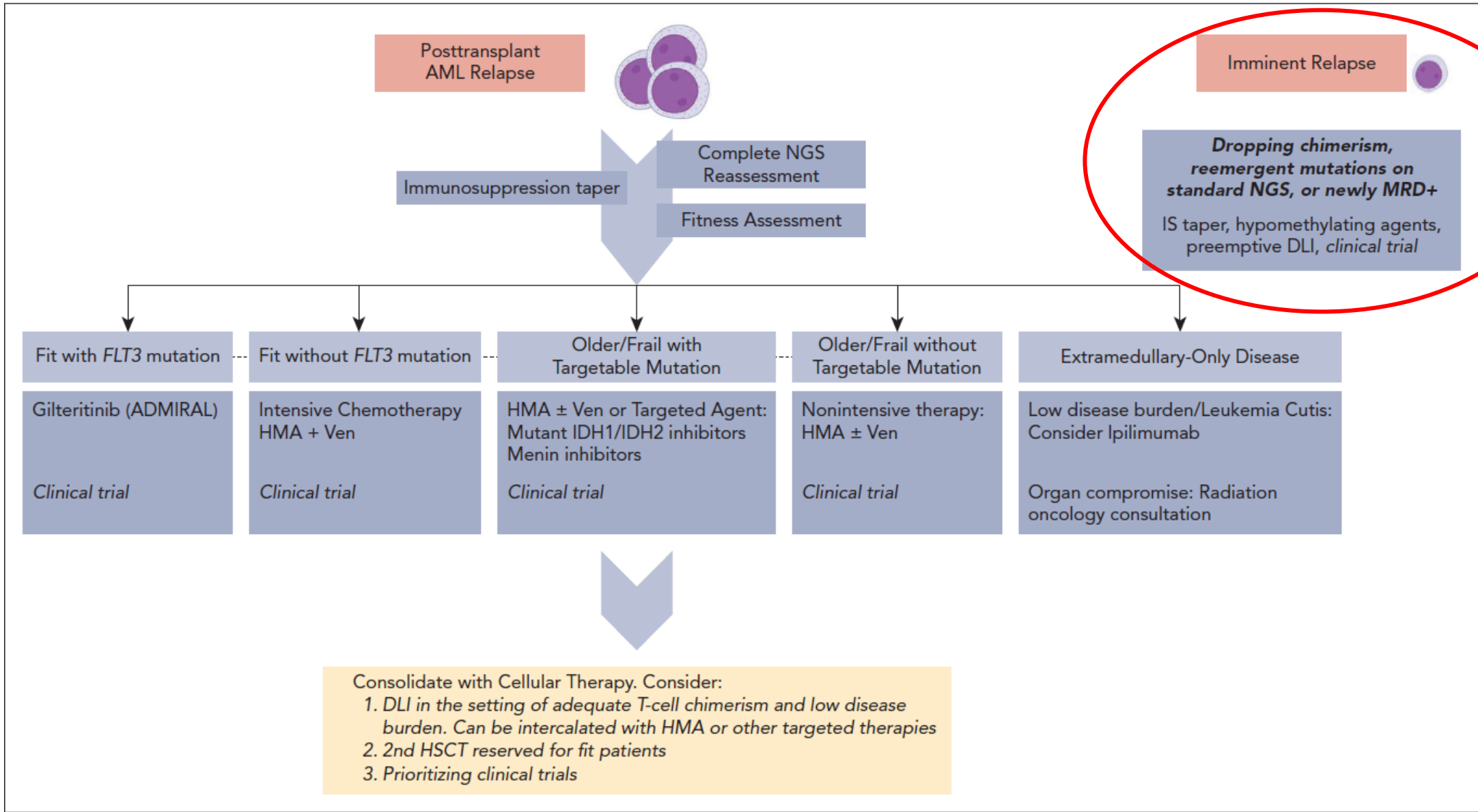
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Univariable and Multivariable analysis on OS (Others)

Variables	Unit of measure / Category	Mean(SD) or n (%)	HR (univariable)			HR (multivariable)		
			HR	95%CI	p-value	HR	95%CI	p-value
Age at the baseline	Years	50.55 (12.20)	1.01	1.00-1.02	p=0.009	1.02	1.01-1.03	p<0.001
Relapse time *	<12 months	258 (76.1)	0.29	0.01-0.78	p=0.014	0.19	0.07-0.54	p=0.002
	≥ 12 months	81 (23.9)						
Relapse disease burden	HIGH	289 (85.3)	0.34	0.22-0.52	p<0.001	0.32	0.19-0.54	p<0.001
	LOW	50 (14.7)						
Diagnosis at SCT	AML	310 (91.4)	1.41	0.93-2.12	p=0.106			
	MDS	29 (8.6)						
Disease status at SCT *	No-CR	96 (28.3)	0.62	0.48-0.80	p<0.001	0.53	0.40-0.69	p<0.001
	CR	243 (71.4)						
Lines therapy	>1	143 (45.5)	0.77	0.60-0.99	p=0.045			
	1	171 (54.5)						
Donor (Sibling as reference) *	Sibling	107 (31.7)	0.92	0.70-1.21	p=0.482			
	MUD/MMUD/U	165 (48.8)						
	Haploidentical	66 (19.5)						
Stem Cells' source (BM as reference)	BM	77 (22.7)	1.26	0.94-1.68	p=0.124			
	PBSC	260 (76.7)						
	UCB	2 (0.6)						
Myeloablative conditioning	NO	73 (21.5)	0.76	0.57-1.01	p=0.059			
	YES	266 (78.5)						
aGVHD (NO as reference)	NO	188 (55.5)	0.98	0.74-1.30	p=0.887			
	YES	96 (28.3)						
	Grade II/IV	55 (16.2)						
GVHD post DLI	NO	292 (89.8)	0.73	0.48-1.12	p=0.148			
	YES	33 (10.1)						
Post relapse first-line DLI based therapy *	NO	228 (67.3)	0.65	0.50-0.84	p=0.001			
	YES	111 (32.7)						
Therapy (Intensive CHT as reference)	Intensive CHT	144 (42.5)	0.65	0.46-0.90	p=0.009	0.50	0.35-0.71	p<0.001
	FLT3-inhibitors	76 (22.4)						
	2nd allo-SCT	21 (6.2)						





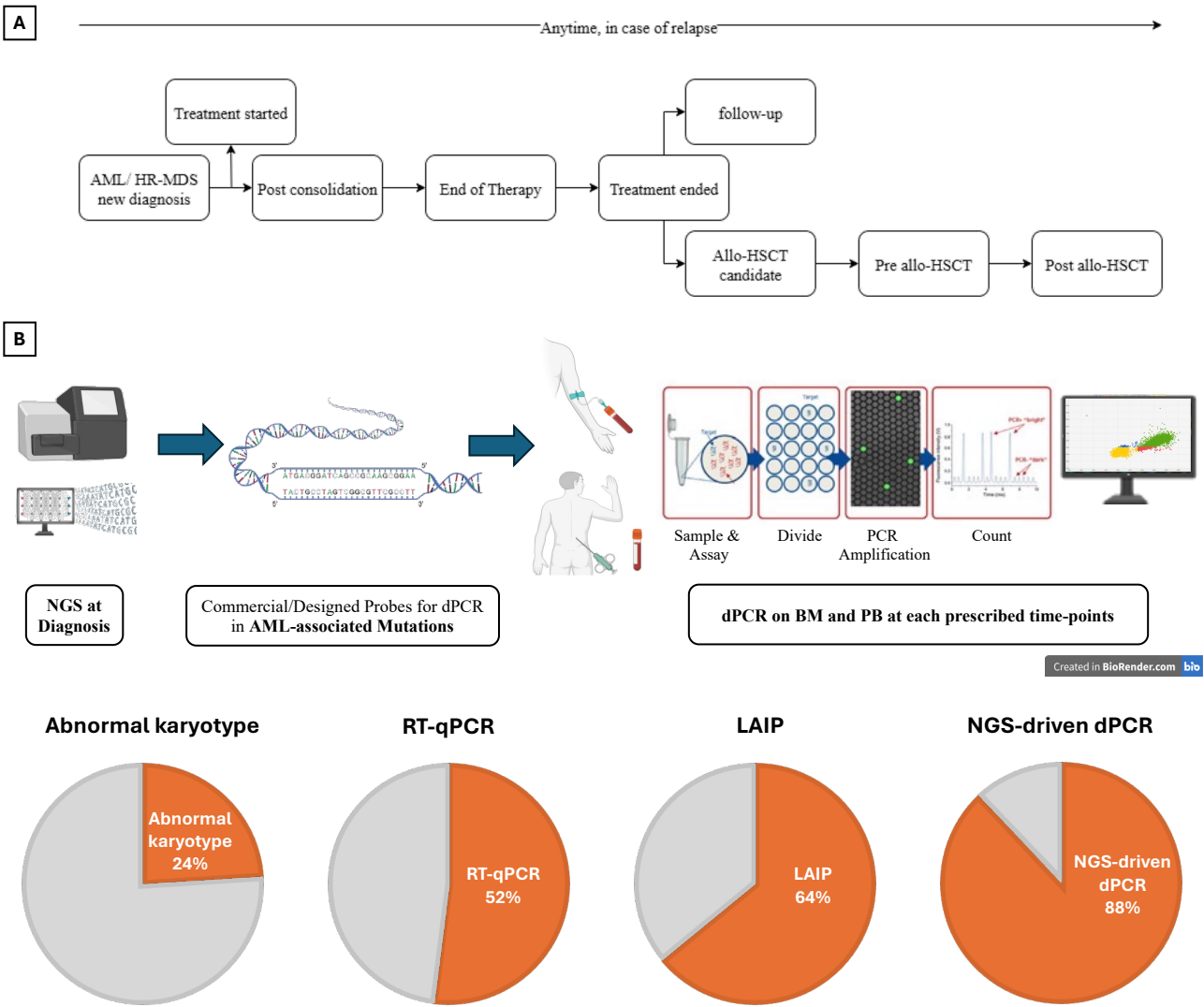
Gooptu E e al, How I treat, Blood 2025

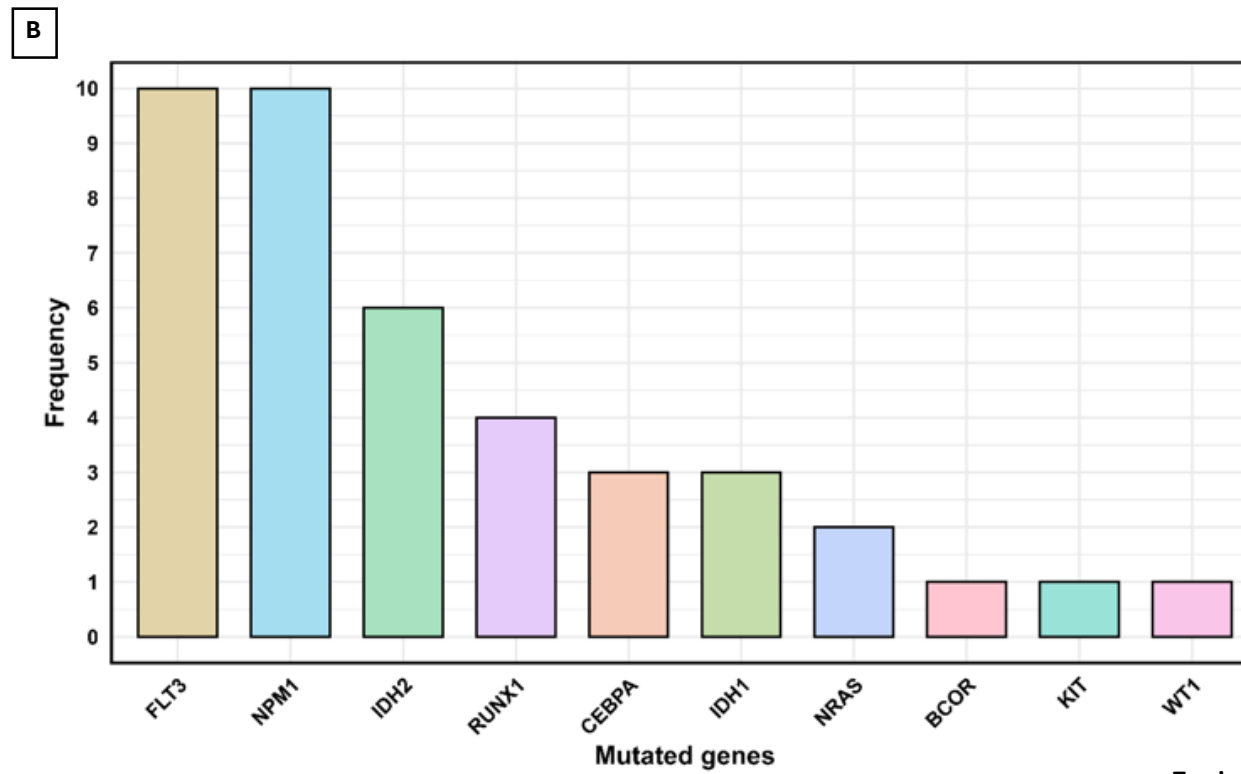
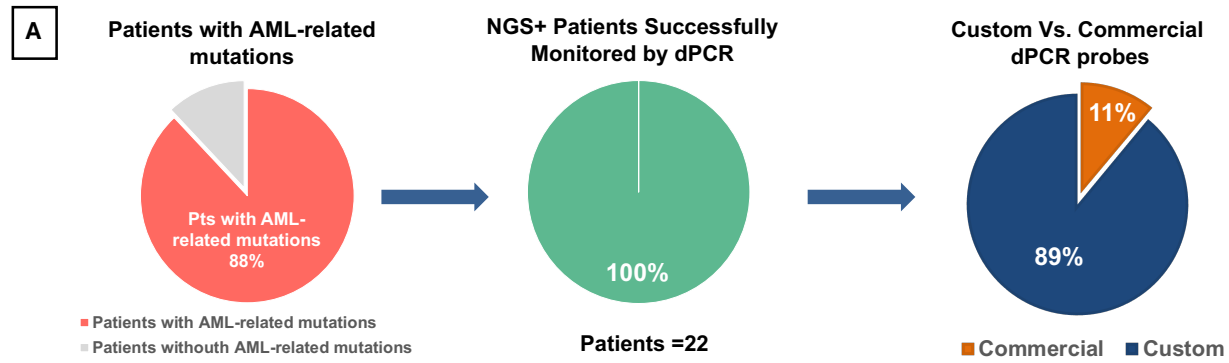


NGS-driven digital PCR for personalized and accurate Measurable Residual Disease assessment in Acute Myeloid Leukemia

Farina M,....., Malagola M, Russo D

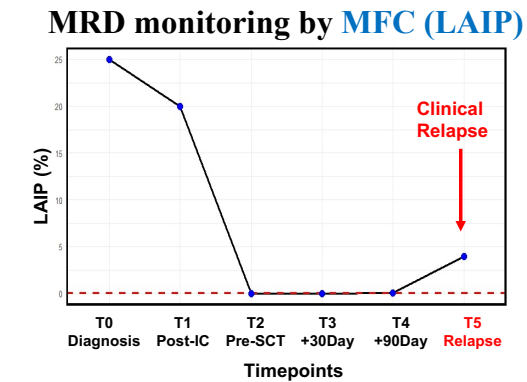
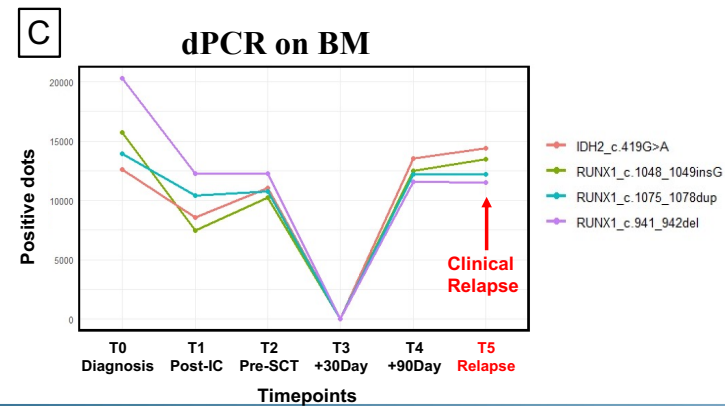
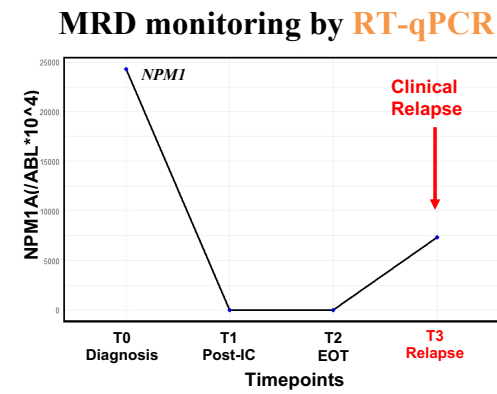
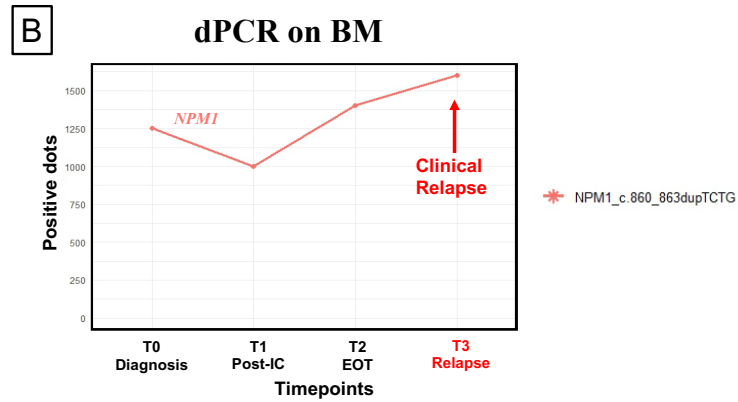
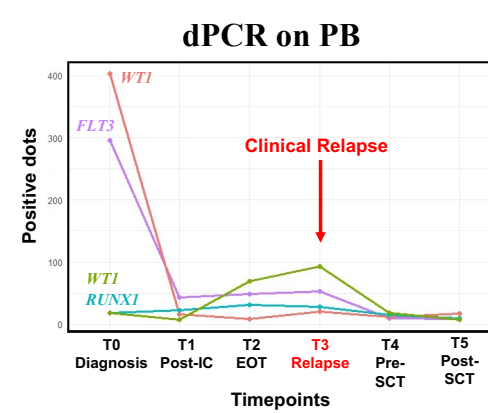
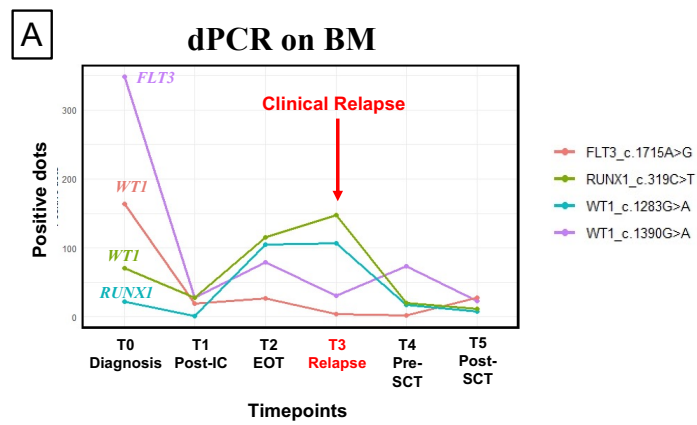
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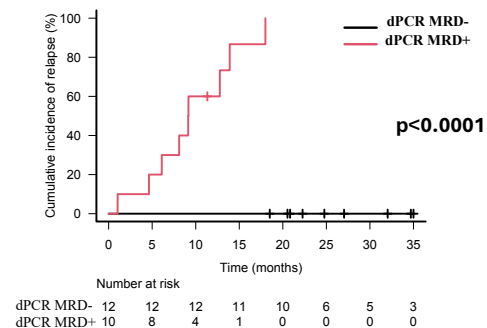




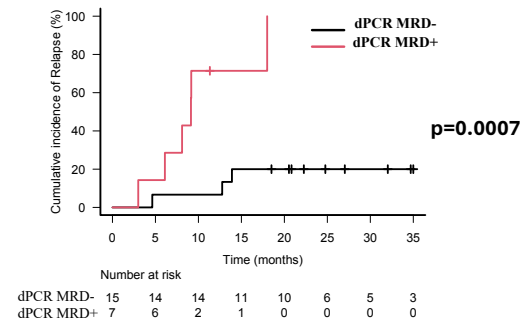
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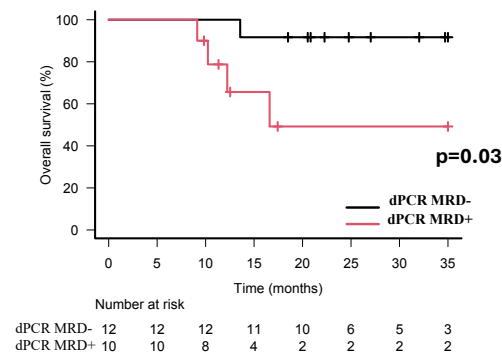
dPCR MRD – Cumulative incidence of Relapse



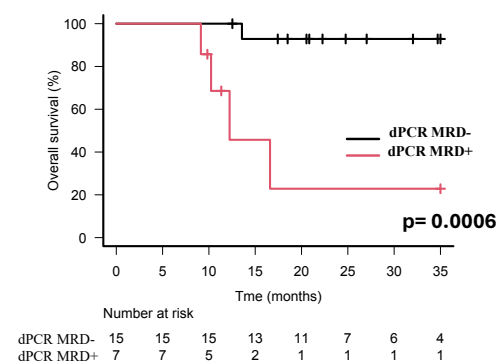
Post consolidation dPCR MRD - Cumulative incidence of Relapse



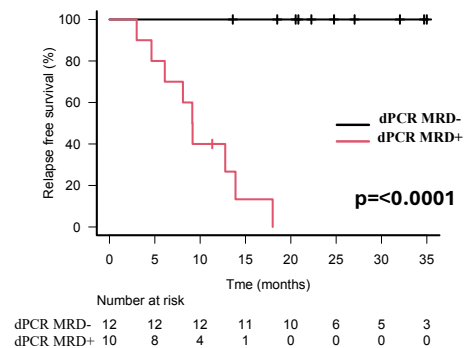
dPCR MRD - Overall survival



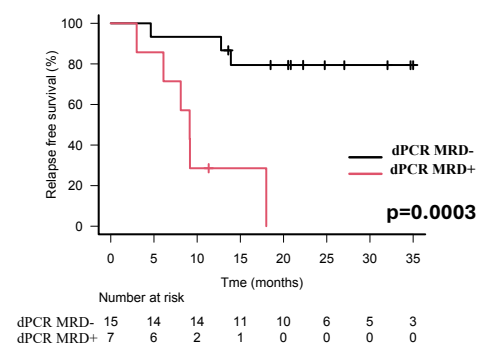
Post consolidation dPCR MRD - Overall survival



dPCR MRD – Relapse free survival



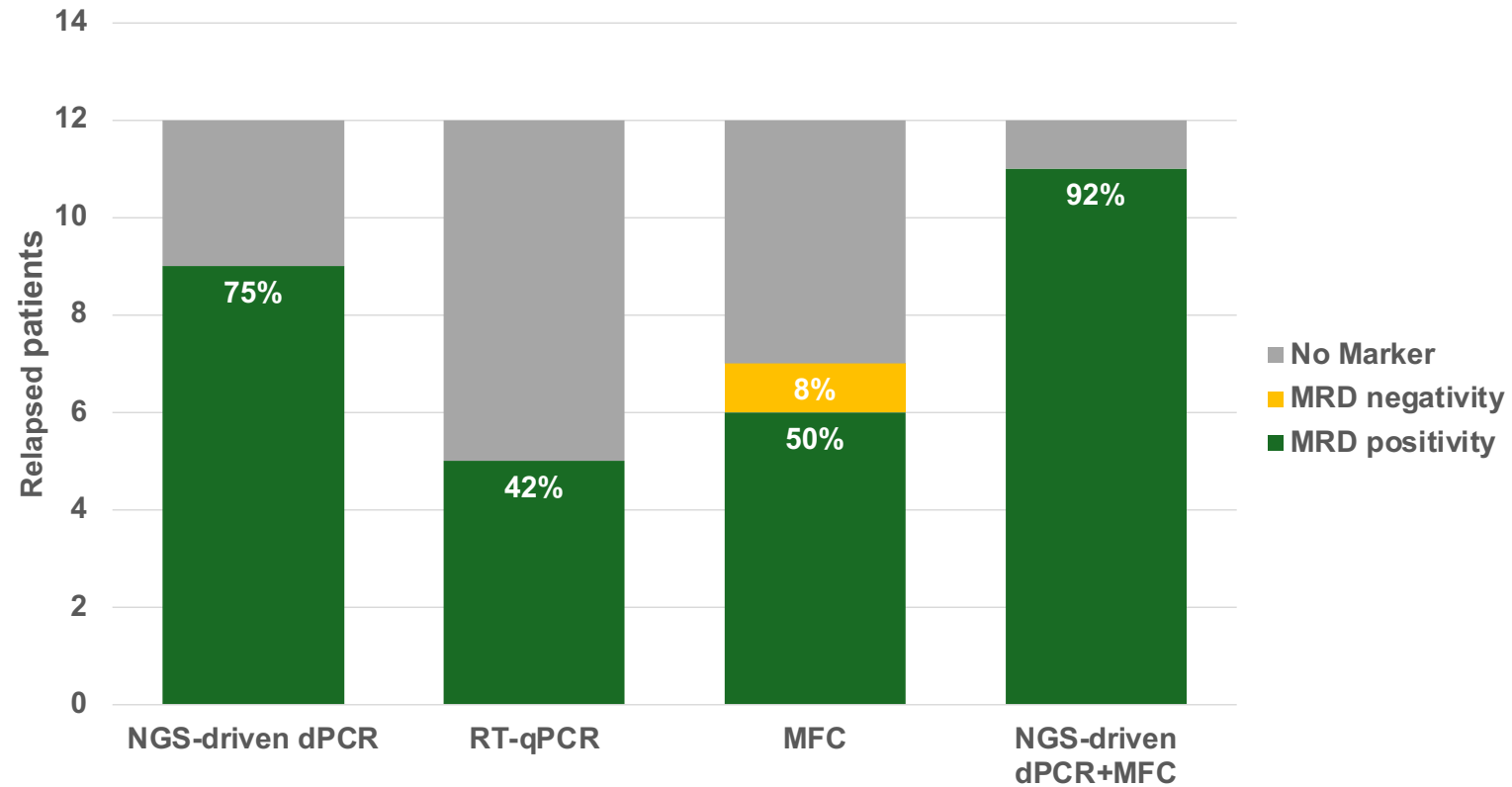
Post Consolidation dPCR MRD – Relapse free survival



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MRD Monitoring Strategies in Relapsed Patients



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