



Newly diagnosed myeloma < 66 years IFM / DFCI prospective study

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on behalf of the IFM/DFCI



« optimal strategy »

Induction therapy

VRD x 3

ASCT

Melphalan
200 mg/m²

Consolidation

VRD x 2

Maintenance

Lenalidomide

**< 66 years, de novo
Pilot trial, IFM 2008-01,
« optimal strategy »**

Induction therapy

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STUDY DESIGN

Open-label, multicenter, phase II study
in frontline MM pts < 65 yrs

Induction treatment = Cycles VRD 1,2 and 3 every 21 days

Lenalidomide 25mg/d (days 1 to 14)

Bortezomib 1.3mg/m² (days 1, 4, 8, 11)

Oral Dexamethasone 40mg/d (days 1, 8, 14)

Response assessment



Peripheral Stem Cell Collection $\geq 5 \times 10^6$ /kg (cyclophosphamide 3g/m² and G-CSF 5 μ g/kg/d)

Response assessment



ASCT

Melphalan 200mg/m² on D-2 + Pegfilgrastim 6mg D2

Response assessment



Consolidation treatment = Cycles VRD 4 and 5, every 21 days

Response assessment



Maintenance therapy for 12 months

Lenalidomide 10mg/d for 3 months then 15mg/d if well tolerated



RESPONSE RATES (ITT)

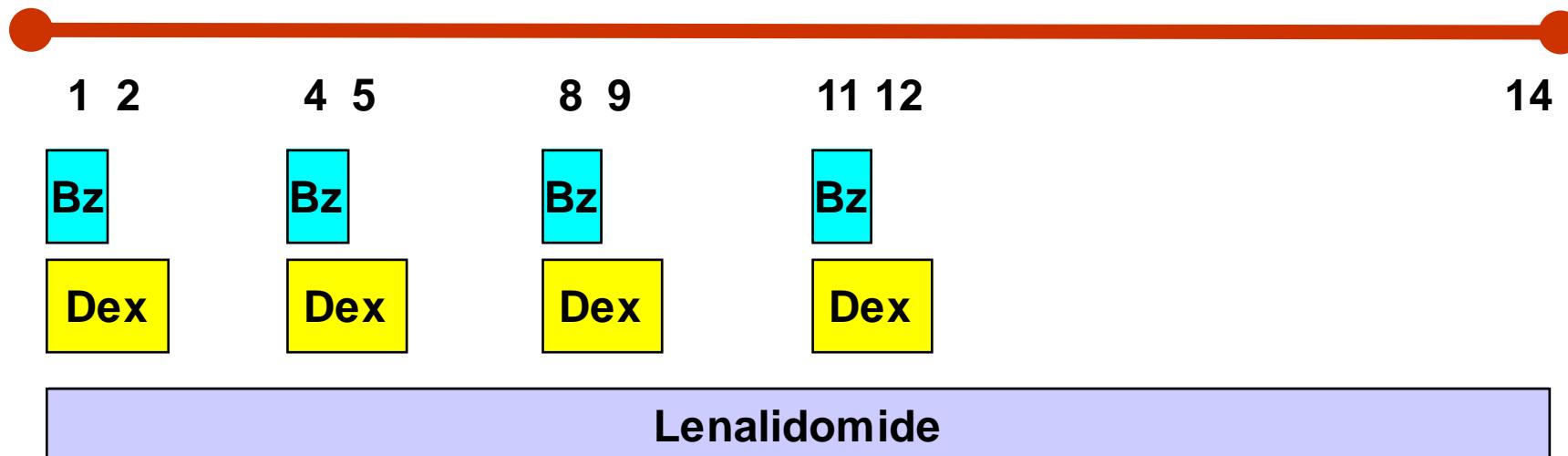
	after Induction		after ASCT		after Consolidation	
	n	%	n	%	n	%
sCR	5	17	10	32	12	38
CR	2	6	3	10	3	10
CR+sCR	7	23	13	42	15	48
VGPR	12	39	8	26	11	36
≥ VGPR	19	62	21	68	26	84
PR	10	32	7	23	3	10
ORR	29	94	28	91	29	94
SD	2	6	2	6	1	3
out of trial	0		1	3	1	3
total	31	100	31	100	31	100

Roussel, ASH 2010

RVD

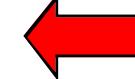
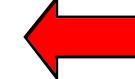
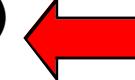
Richardson et al, Blood 2010, online 12 april

Up to eight 21-day cycles

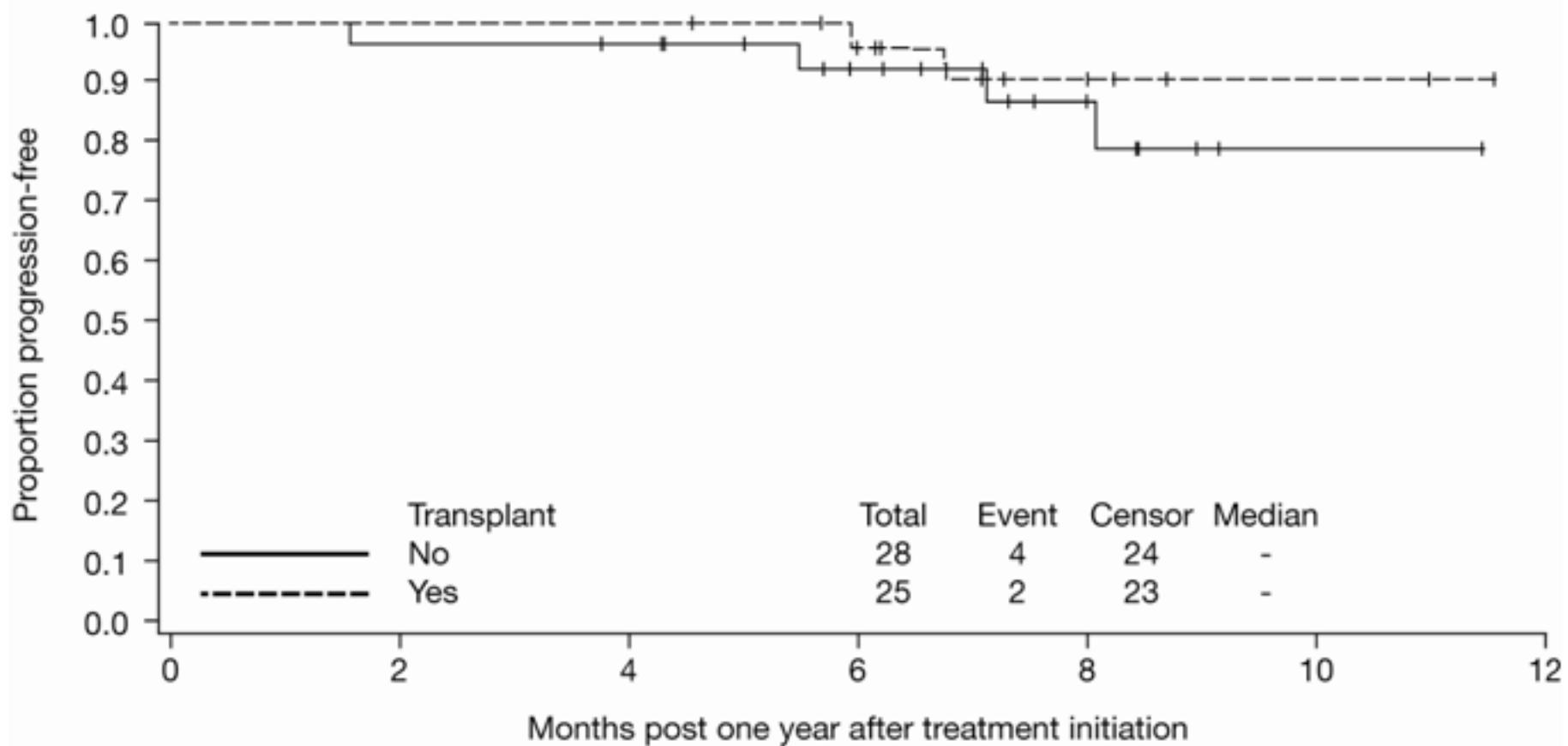


Phase II : Len 25, Btz 1.3, Dex : 20

Best response to treatment overall and in the phase II population

Response, n (%)	All pts (N=66)	Phase II (N=35)
CR	19 (29)	13 (37)
nCR	7 (11)	7 (20)
VGPR	18 (27)	6 (17)
PR	22 (33)	9 (26)
CR+nCR	26 (39)	20 (57) 
CR+nCR+VGPR	44 (67)	26 (74) 
At least PR	66 (100)	35 (100) 

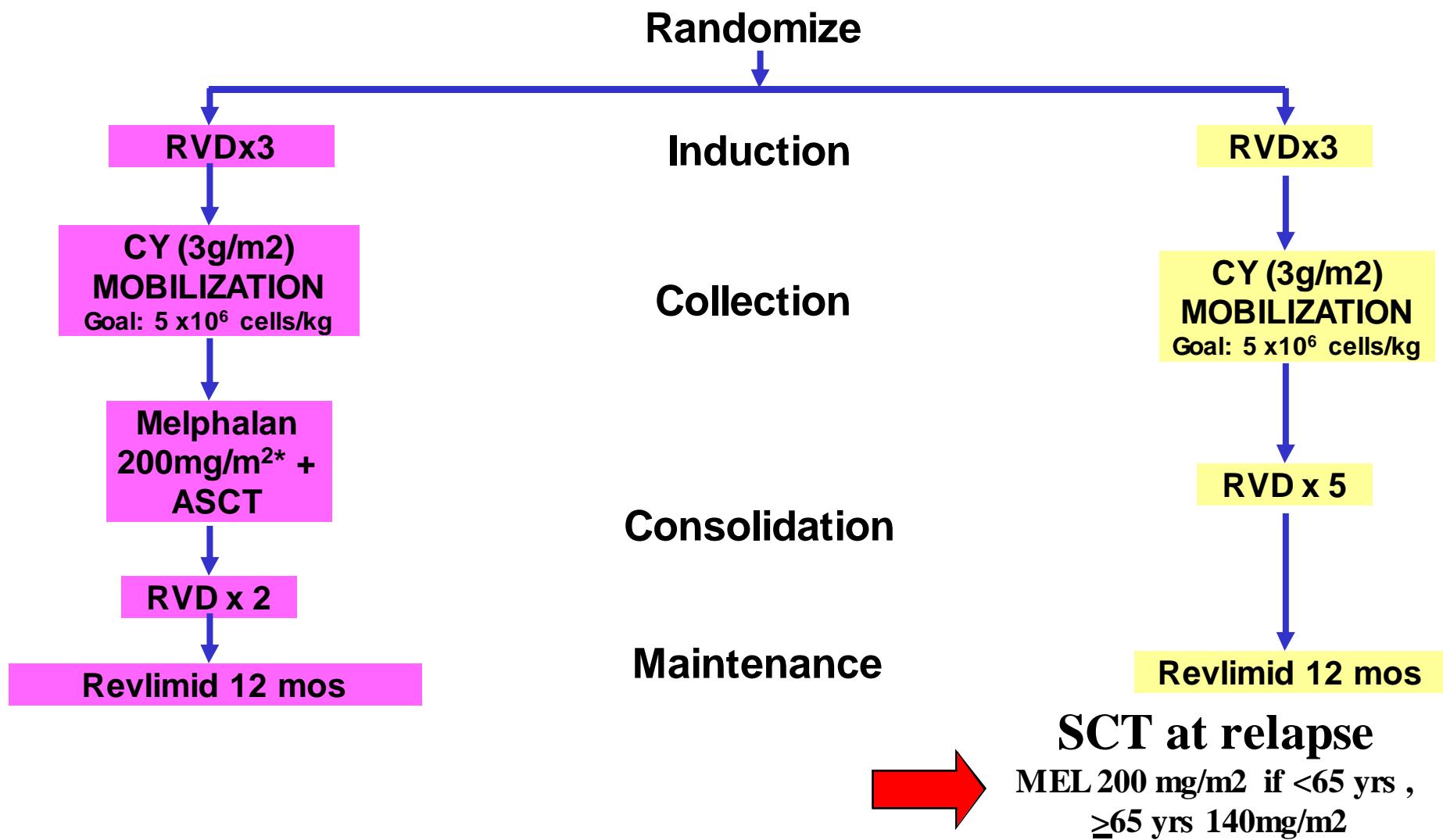
PFS according to receipt of ASCT



Receipt of ASCT did not affect 1-yr PFS ($P = .38$)

IFM/DFCI 2009 Study

Newly Diagnosed MM patients



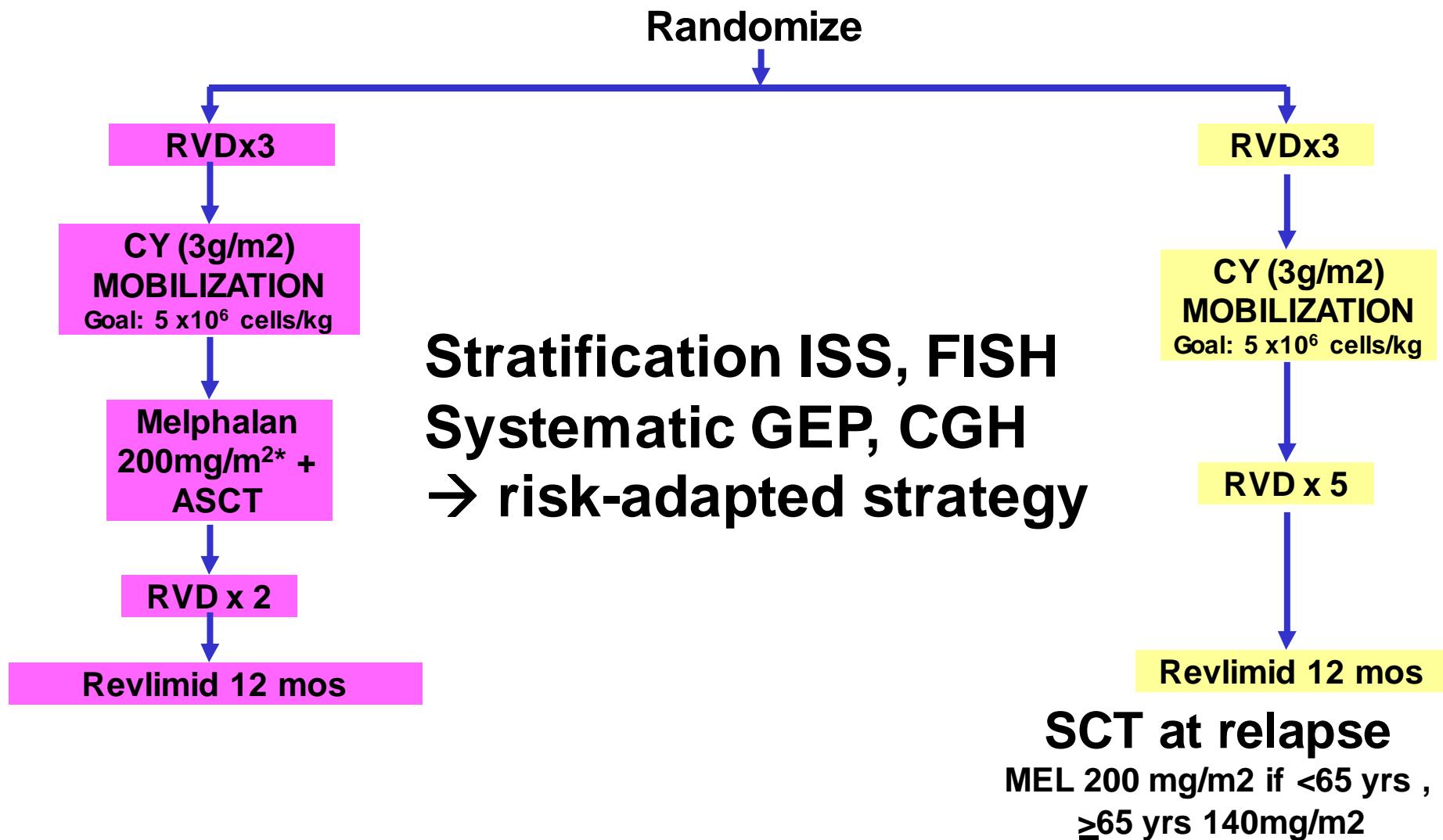
IFM/DFCI 2009 Study

Newly Diagnosed MM patients

Primary end-point:
PFS, 30 months vs 39 months

1000 patients

IFM/DFCI 2009 Study Newly Diagnosed MM Patients



IFM/DFCI 2009 Study

Newly Diagnosed MM patients

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