

A PROSPECTIVE, RANDOMIZED STUDY OF MELPHALAN, PREDNISONE, LENALIDOMIDE (MPR) VERSUS MELPHALAN 200 mg/m² (MEL200) IN NEWLY DIAGNOSED MYELOMA PATIENTS: AN INTERIM ANALYSIS

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Disclosures for Palumbo Antonio, MD

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Consultant	No relevant conflicts of interest to declare
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Speakers Bureau	No relevant conflicts of interest to declare
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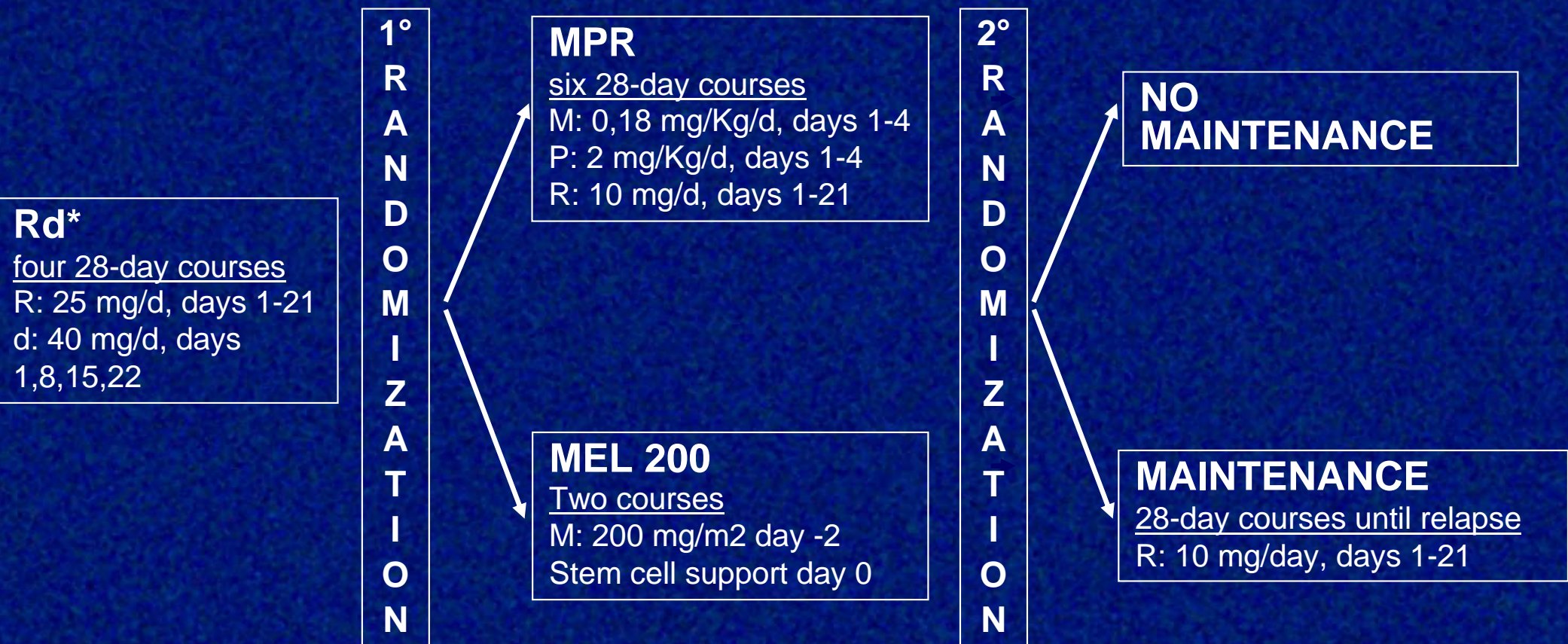
Aims

Safety and efficacy of **Rd induction** before ASCT

- Comparison between:
 - **Conventional chemo** incorporating new drug
 - **ASCT** incorporating new drug
- Role of lenalidomide **maintenance** after chemo/ASCT

Treatment schedule

- 402 patients (younger than 65 years) randomized from 62 centers
- Patients: Symptomatic disease, organ damage, measurable disease

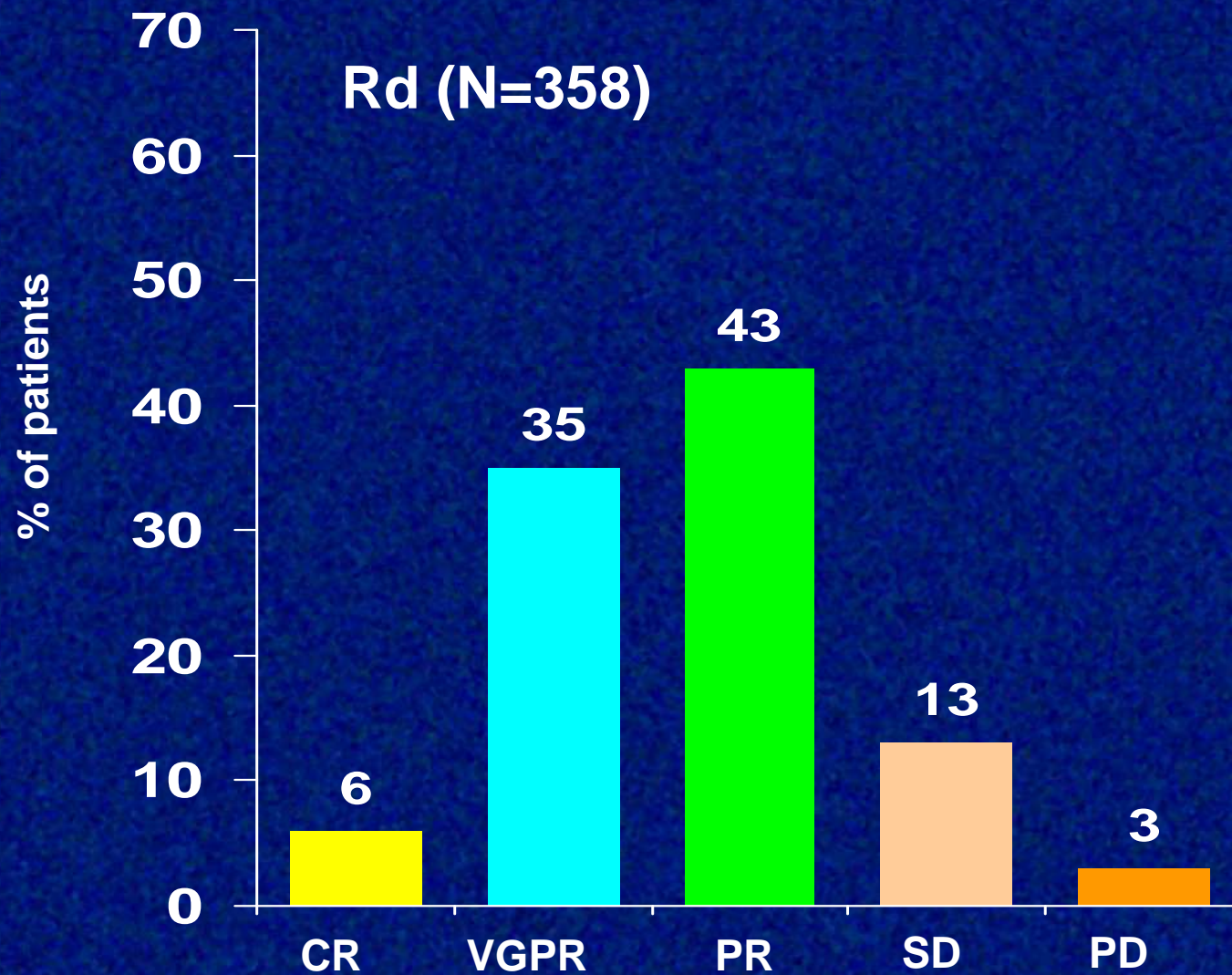


*Thromboprophylaxis randomization: aspirin vs low molecular weight heparin
R, lenalidomide; M, melphalan; d, dexamethasone; P, prednisone

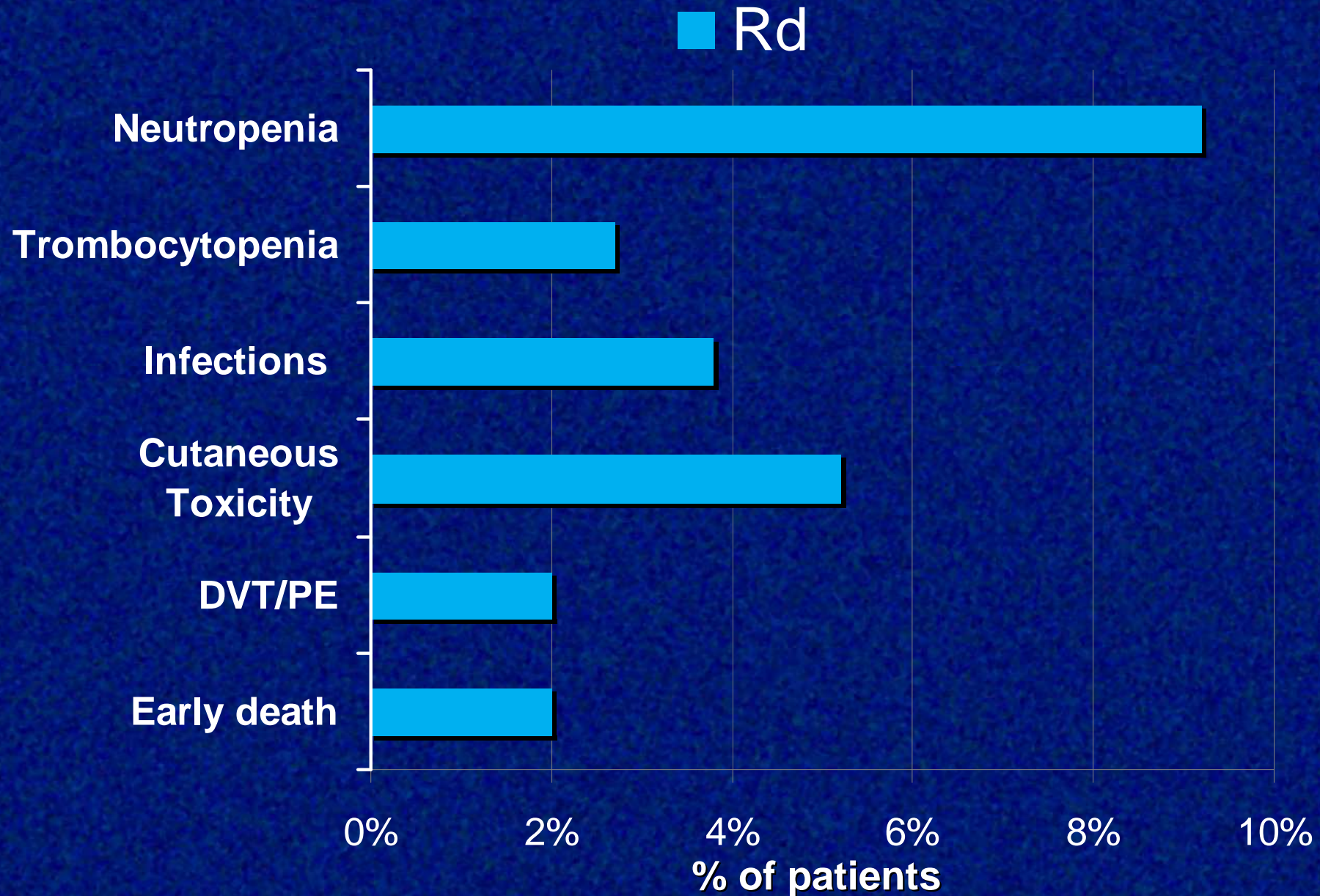
Patient Characteristics

	MPR (N=202)	MEL200 (N=200)
Age (median)	58	58
< 60 years	24%	29%
ISS (%)		
I + II	76	76
III	25	24
del 13 (pos %)	57	47
del 17 (pos %)	17	13
t(4;14) (pos %)	16	13

Rd: Best Response



Rd: Grade 3-4 Adverse Events



DVT: deep vein thrombosis; PE: pulmonary embolism

Thromboprophylaxis for Lenalidomide ASA vs Low Molecular Weight Heparin

Study Design

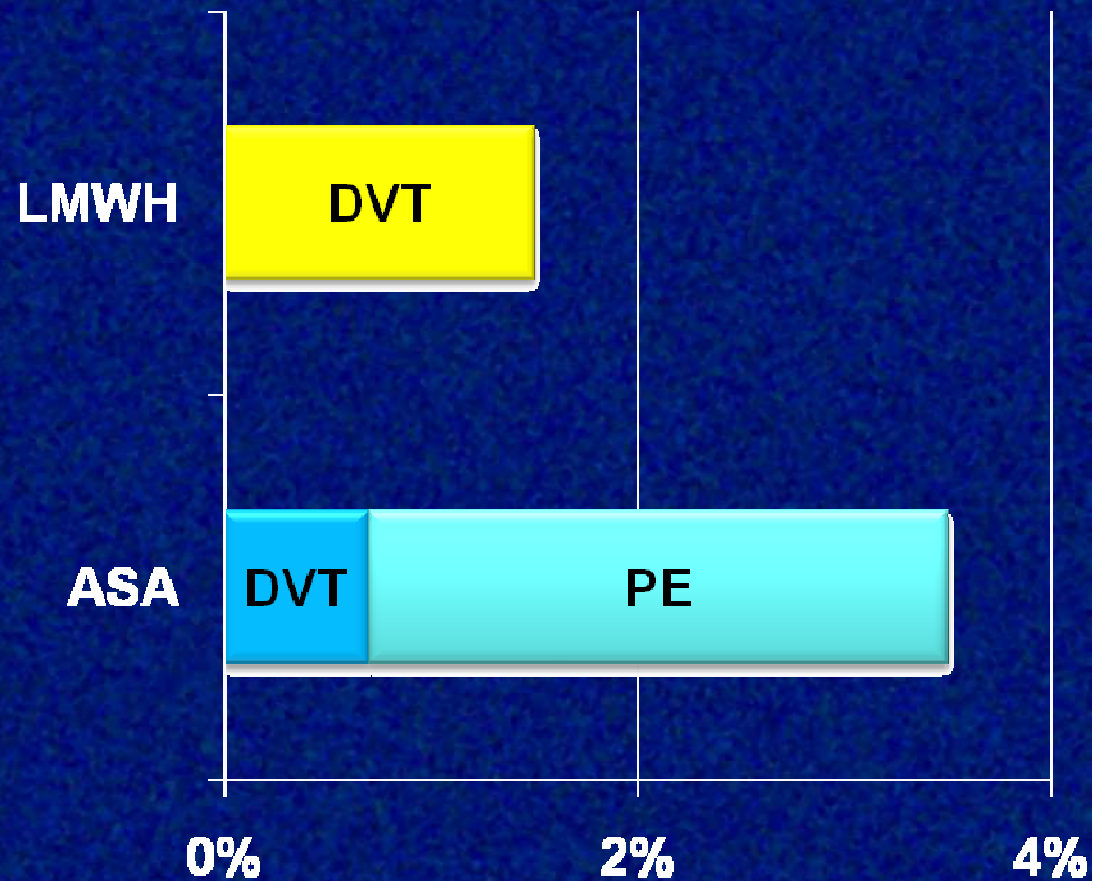
Rd induction

RANDOMIZATION

ASA
Aspirin
100 mg/day

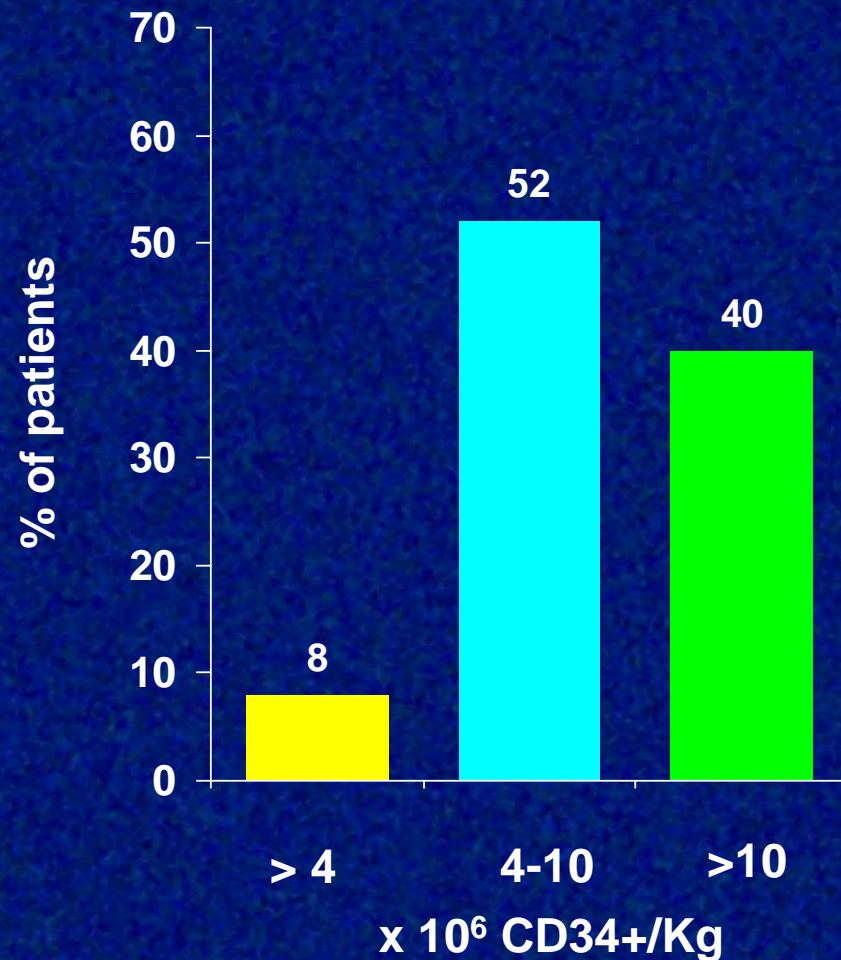
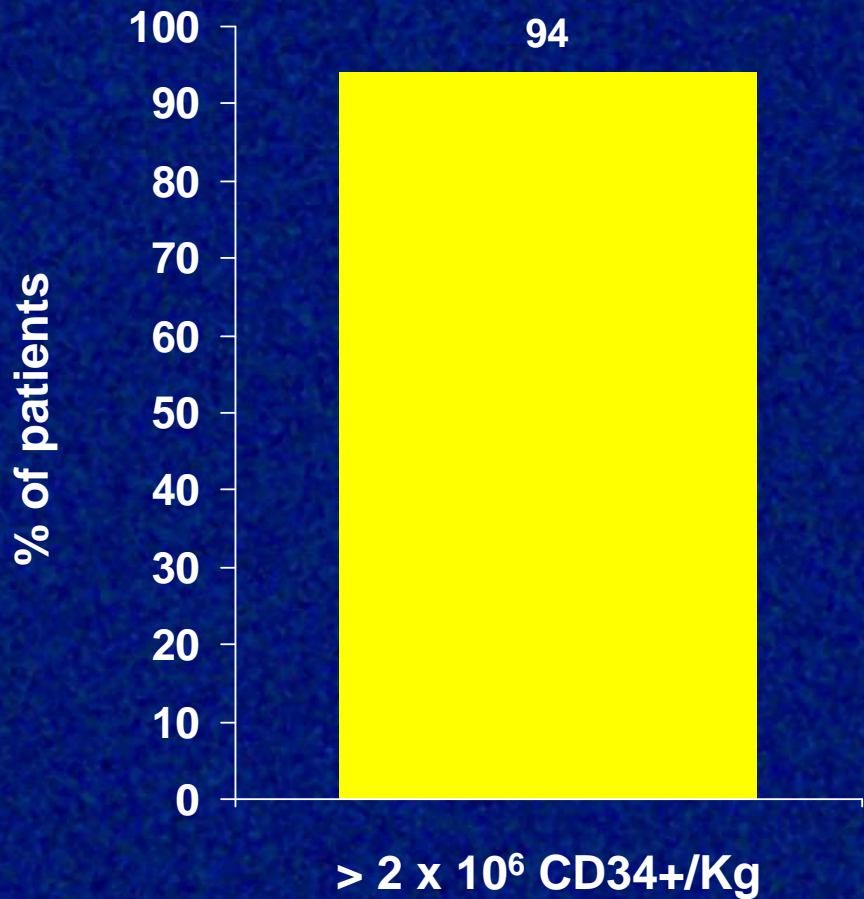
LMWH
Enoxaparin
40 mg/day

Risk of VTE

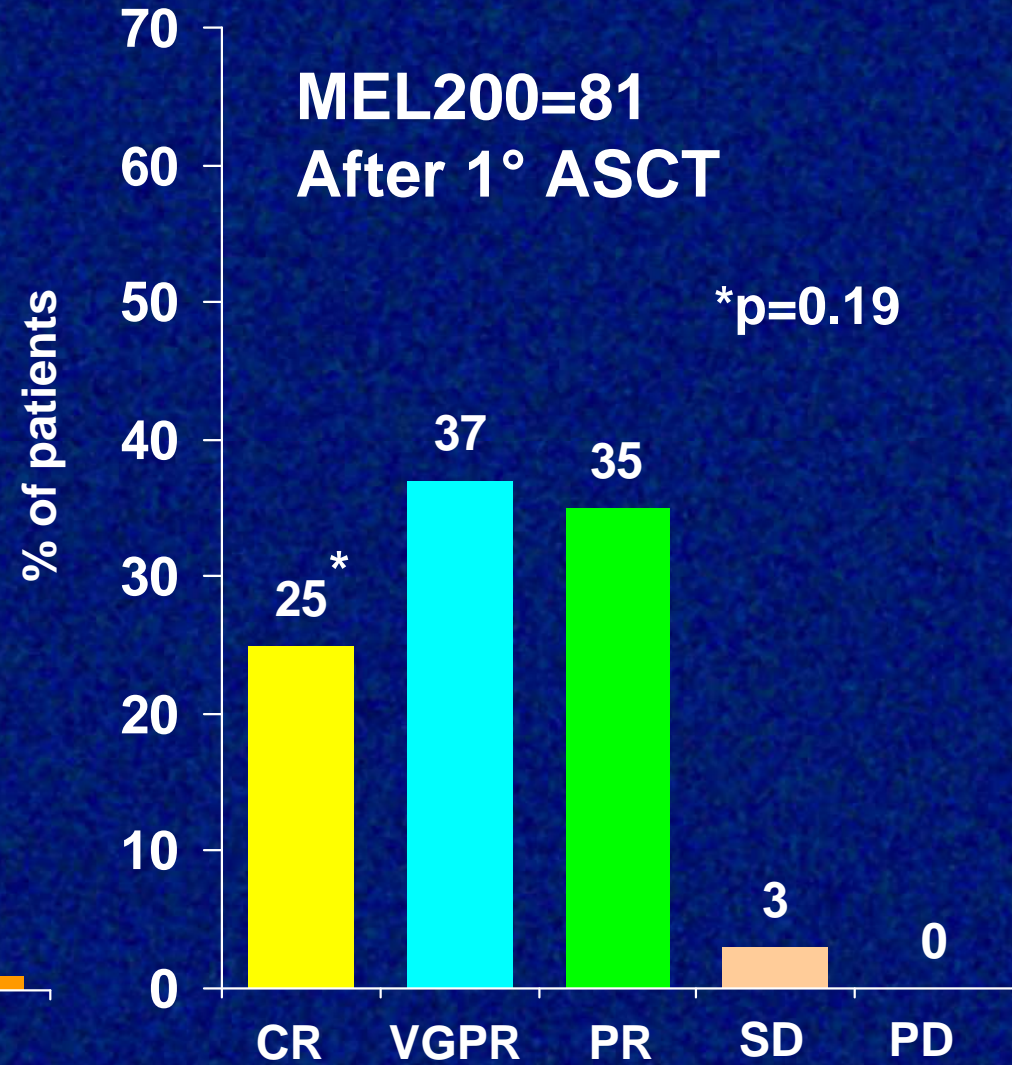
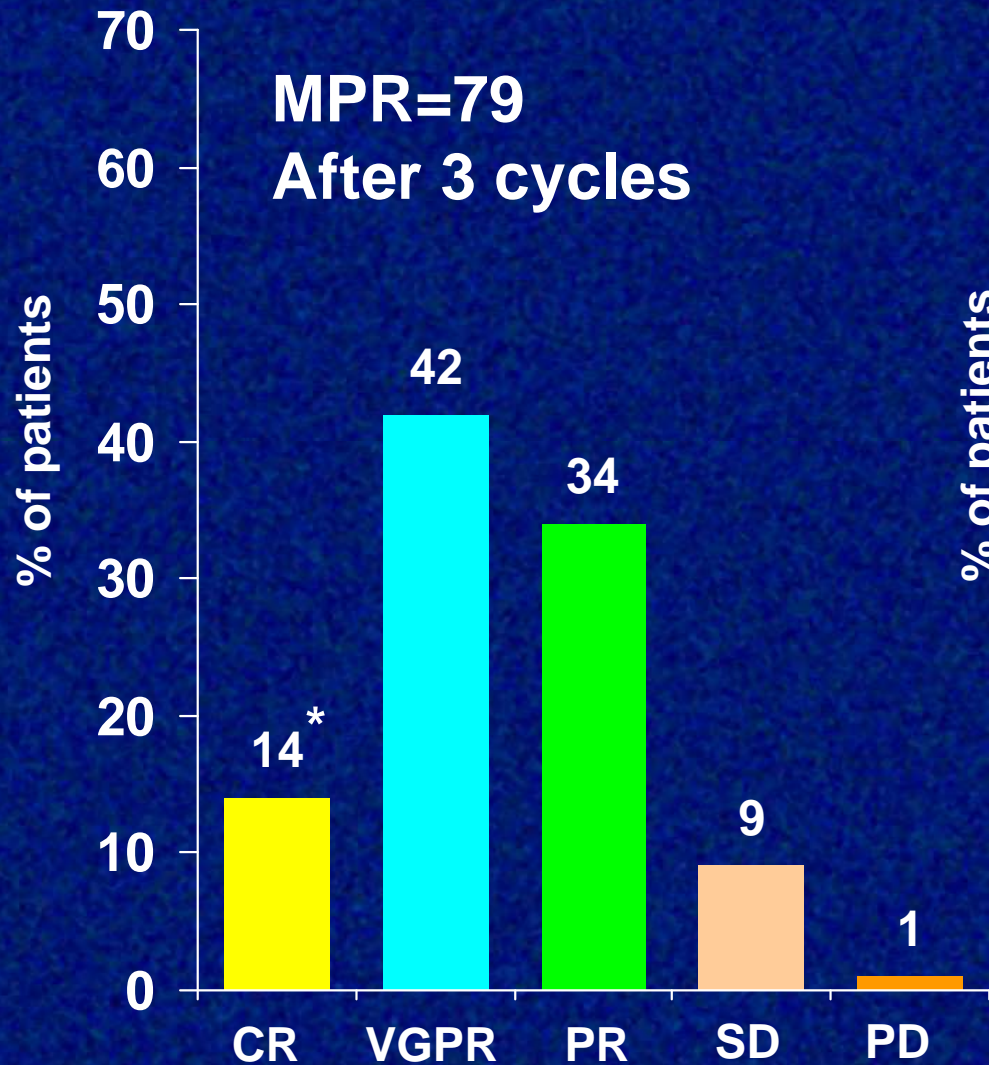


Stem cell mobilization data

- Patients received Cy 4g/sqm + GCSF one month after Rd induction
- Median collection: **8.85 x10⁶ CD34+/Kg**



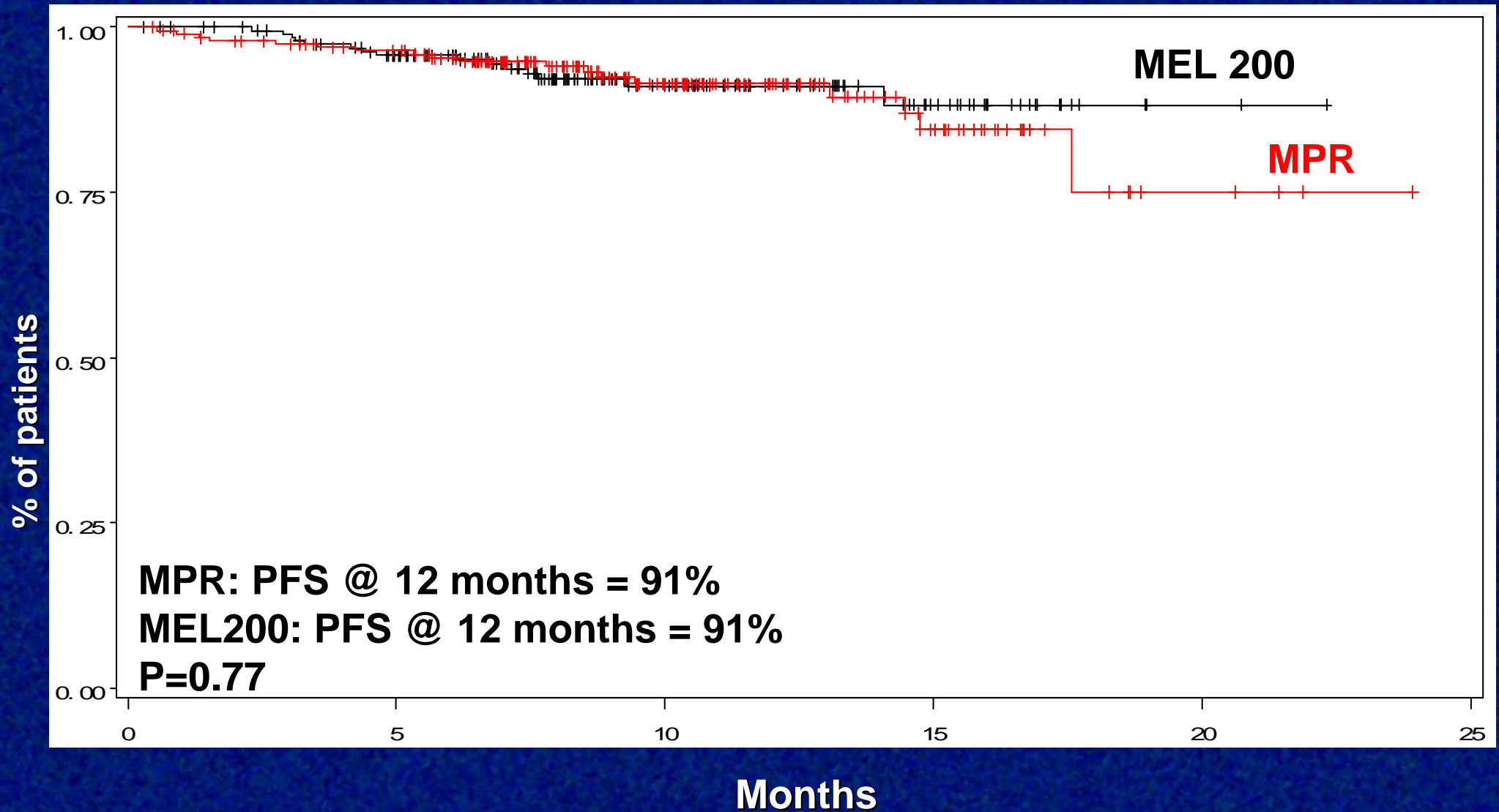
MPR vs MEL200: Response rate[§]



[§]Per protocol

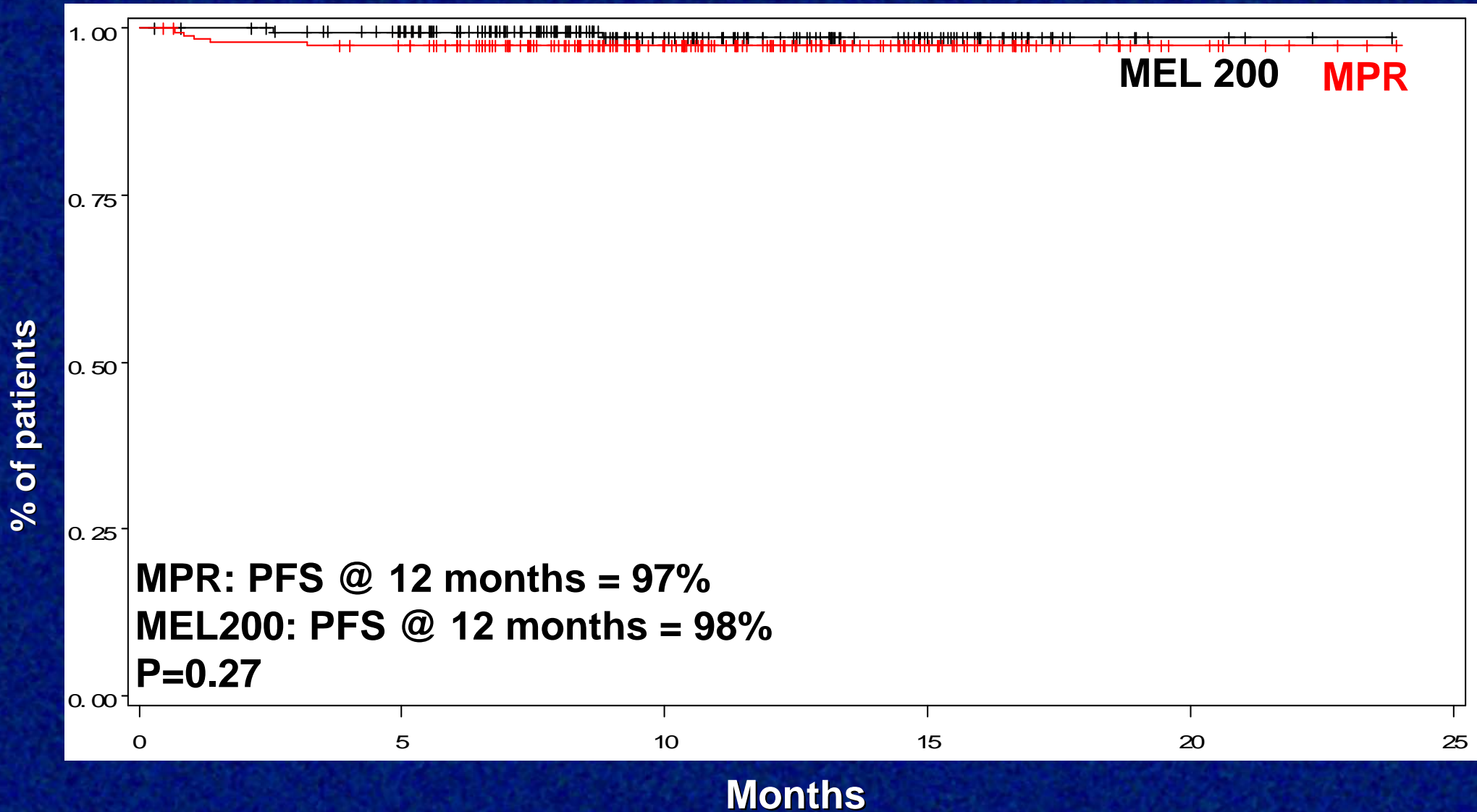
MPR vs MEL200: Progression Free Survival

Median follow-up 9 months



MPR vs MEL200: Overall survival

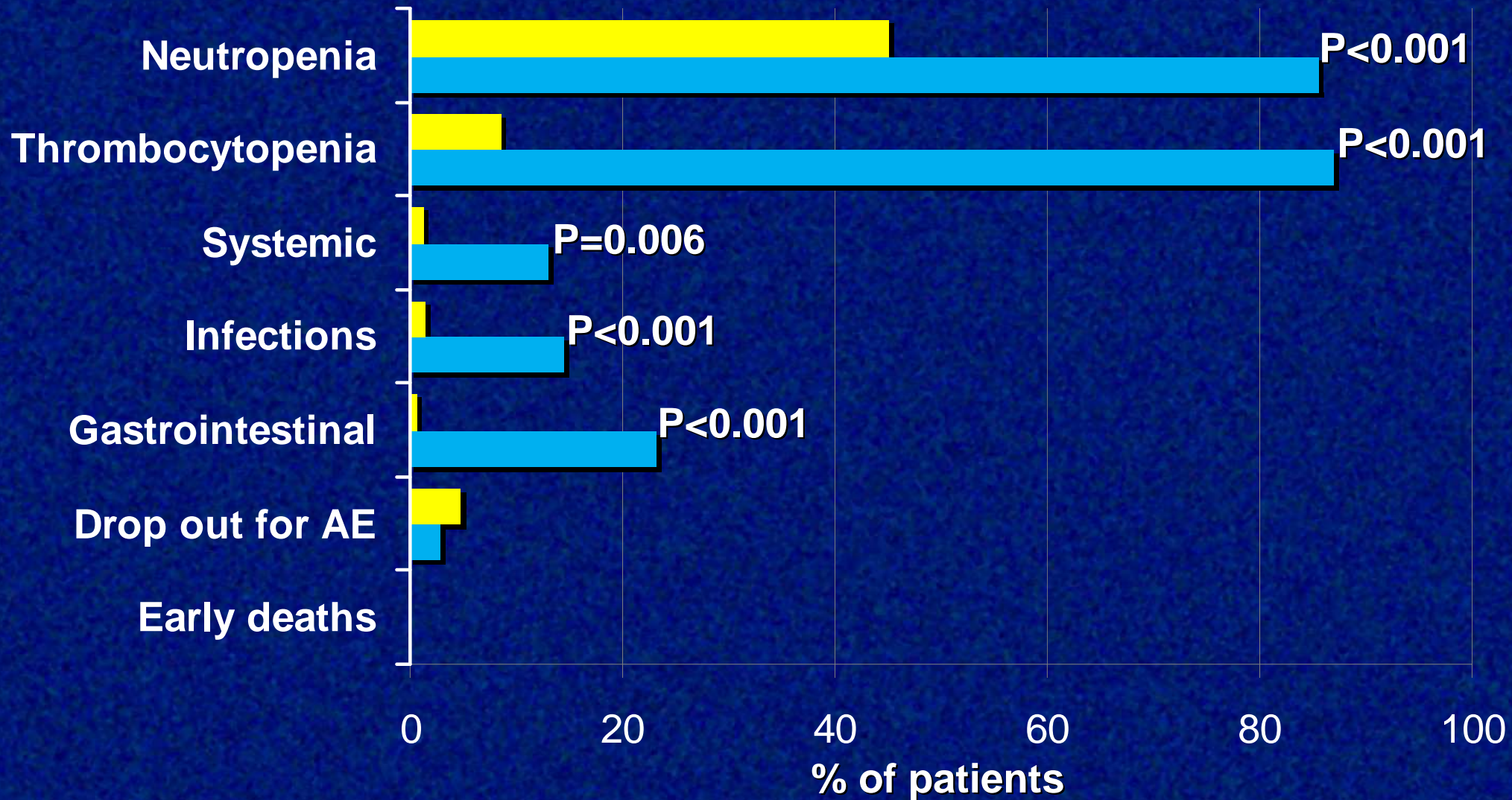
Median follow-up 9 months



MPR vs MEL200

Grade 3–4 Adverse Events

■ MEL200 (n=81) ■ MPR (n=79)



Conclusions 1

	MPR	MEL200	P value
CR	14%	25%	0.19
≥ VGPR	57%	62%	0.31
PFS @ 12 months	91%	91%	0.77
OS @ 12 months	97%	98%	0.27

Conclusions 2

- **Rd induction effective and excellent safety profile**
- 94% of patients collected $> 2 \times 10^6$ CD34/kg
- Higher CR rate for MEL200 (p=0.19)
- **MPR vs MEL200: no differences in PFS (p=0.77)**
- Longer follow-up is needed to assess PFS and OS

WE ARE GRATEFUL TO ALL PATIENTS, NURSES AND PHYSICIANS OF THE PARTICIPATING CENTERS

1. ALESSANDRIA	Levis, Baraldi	37. FORLI'	Amadori, Gentilini	73. PINEROLO	Griso
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3. AOSTA	Di Vito	39. GALLARATE	Ciambelli	75. POTENZA	Ricciuti, Vertone
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				108. VITERBO	Montanaro