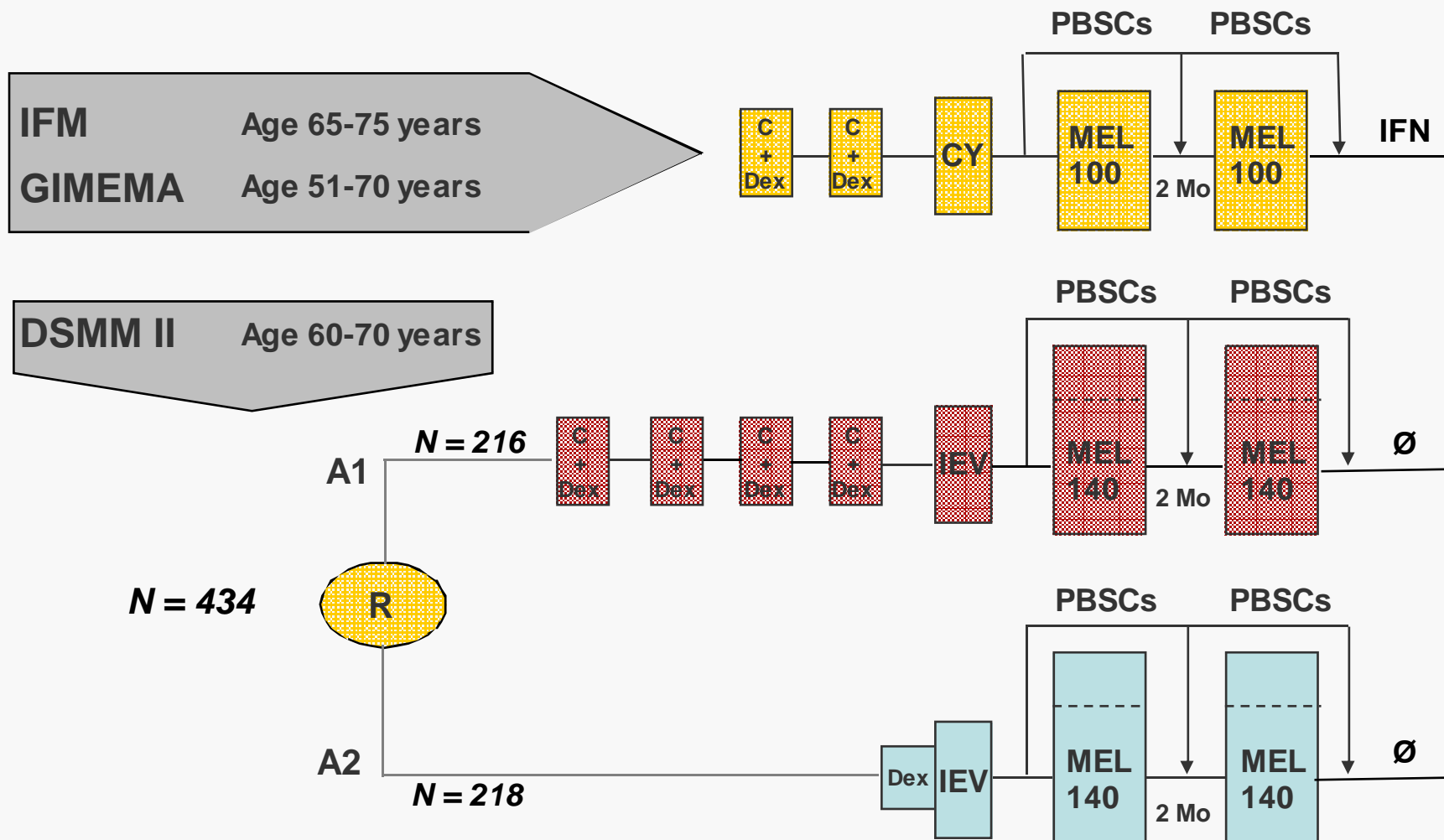


13. International Myeloma Workshop Paris, 05.05.2011

EMNTG – DSMM – Germany

Christian Straka
Berg, Germany

Age-adjusted high-dose melphalan in elderly patients with multiple myeloma



DSMM II – Non-hematological toxicity NCI-Grade 3/4

	1. High-dose Melphalan		2. High-dose Melphalan	
	Induction A1	No Induction A2	Induction A1	No Induction A2
Infection	31 %	45 %	37 %	33 %
Oral Mucositis	7 %	16 %	5 %	6 %

MEL 140 vs MPT vs VMP

Progression and treatment free survival (PTFS)

	GIMEMA	IFM	DSMM II	DSMM II	VISTA
	MP-THAL	MP-THAL	Tandem-MEL 140	Tandem-MEL 140	VMP
			Induction A1	No Induction A2	
Median PFS	29 Months	28 Months	22 Months	20 Months	22 Months
Treatment Time	until progression	17 Months	7 Months	4 Months	13 Months
PTFS			15 Months	16 Months	
OS at 3 years	80 %	68 %	75 %	69 %	69 %
OS Median	45 Months	52 Months	51 Months	52 Months	

GIMEMA: Newly diagnosed MM, 65-75 years, intention-to-treat, n = 102

	After PAD	After tandem MEL100 + ASCT	After LP-L
CR	12 %	33 %	40 %
≥ VGPR	55 %	76 %	78 %
≥ PR	88 %	93 %	93 %

Median follow-up: 21 months

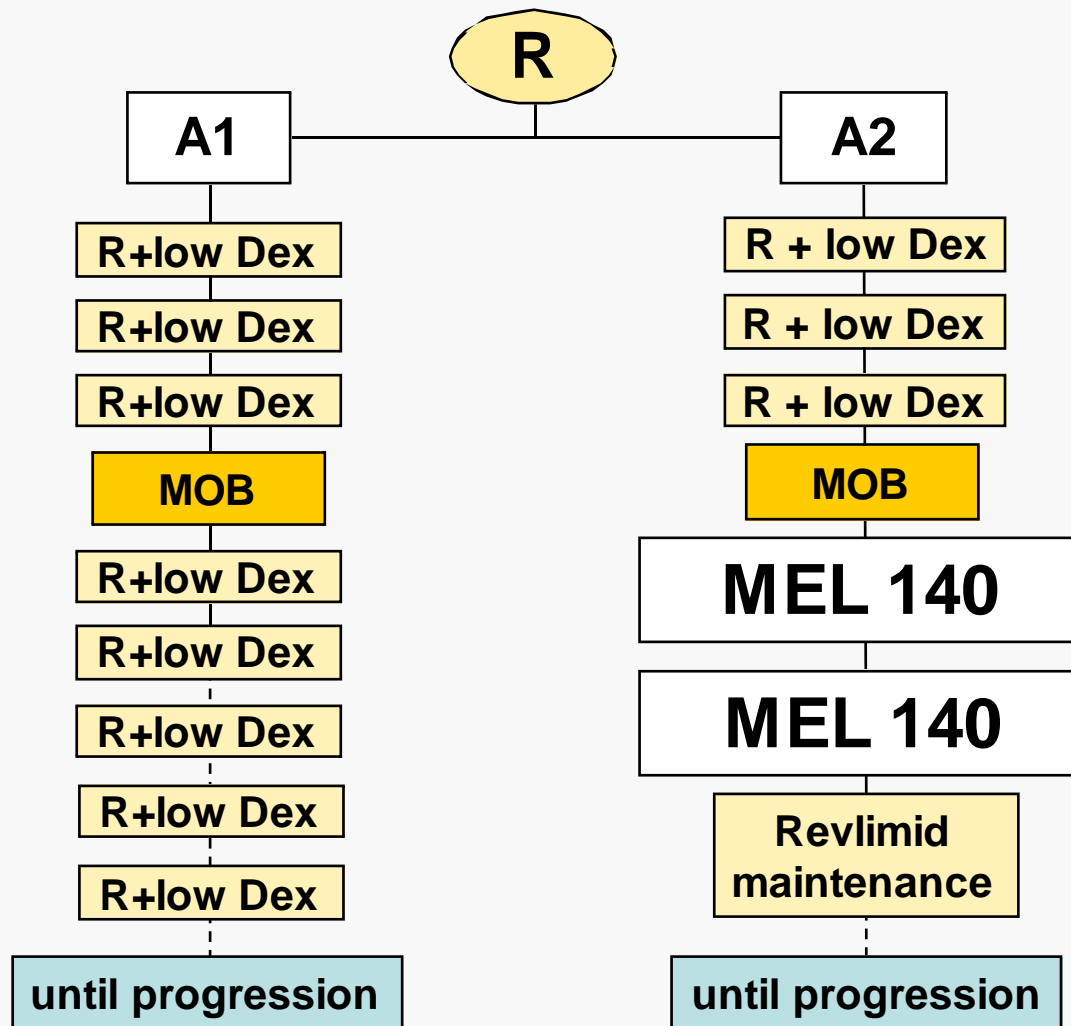
- **2-year PFS 69 %**
- **2-year OS 86 %**

ECOG-E4A03: RD or Rd +/- Transplant

Landmark analysis on patients surviving the first 4 cycles of therapy

	≤ 65 years		> 65 years	
	Continued primary RD or Rd > 4 cycles n = 141	Transplant group n = 68	Continued primary RD or Rd > 4 cycles n = 200	Transplant group n = 22
1-year survival, %	94	100	94	95
2-year survival, %	88	94	81	91
3-year survival, %	78	94	69	83

PI: Ch. Straka



- Randomization
- Rd: Rev 25 mg d 1-21/28
Dex 40 mg d 1,8,15,22
- Mobilization of PBSC (G +/- chemo)
- with autologous PBSC
- with autologous PBSC
- Rev 10 mg per day

DSMM XIII: Asked Questions

- Is there a benefit of age-adjusted high-dose melphalan (140 mg/m²) with autologous blood stem cell transplantation during first-line therapy with novel agents (lenalidomide) in elderly myeloma patients (60-75 years) ?
- Comparison of first-line vs. second-line age-adjusted high-dose melphalan with autologous transplantation

PI: Ch. Straka

Inclusion:

- Age 60 – 75 years
- Symptomatic multiple myeloma (CRAB)
- Measurable disease
- ECOG performance status ≤ 2

Exclusion:

- Renal failure requiring dialysis
- Antithrombotic prophylaxis not possible
- Prior chemotherapy (except short-course Dex)
- Prior Dex toxicity \geq grade 3

Stratification at randomization:

- ISS stage I + II *versus* stage III
- Age ≤ 70 years *versus* > 70 years

Primary end point / statistics:

- Progression-free survival (PFS)
- 10 months difference in PFS, $A2 > A1$. 350 patients

DSMM XIII

Status: April 28, 2011

Centers:

Planned: 35

Initiated: 26

Patients:

Randomized: 69

Central Cytogenetics:

+9q34	66%
del 13q14	26%
+1q21.2	20%
t(4;14)	4%
del 17p13	0
t(14;16)	0

dsmm

centers

Chairmen

Hermann Einsele, Würzburg

Christian Straka, Berg

Participating Centers

> 50 in Germany

Central Cytogenetics, Ulm

Christian Langer

Peter Liebisch

Statistics

Axel Hinke, Langenfeld

CRO ClinAssess, Leverkusen

Burkhard Deuß

Anja Liebert

Marianne Sauerwein

