

NEWLY DIAGNOSED MYELOMA>65 YEARS: FACTS & QUESTIONS

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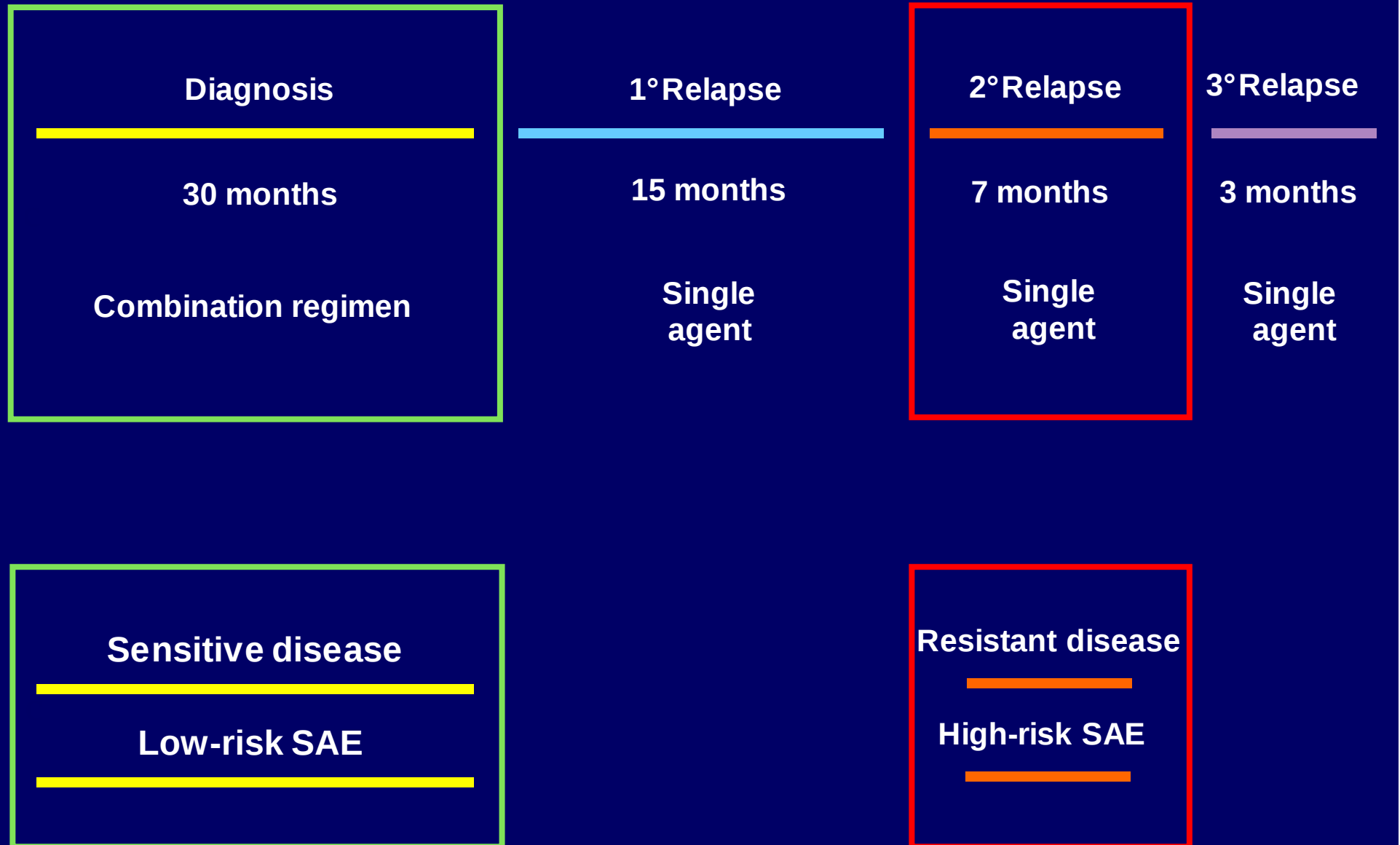
University of Torino, Torino, I, EU

On behalf of the



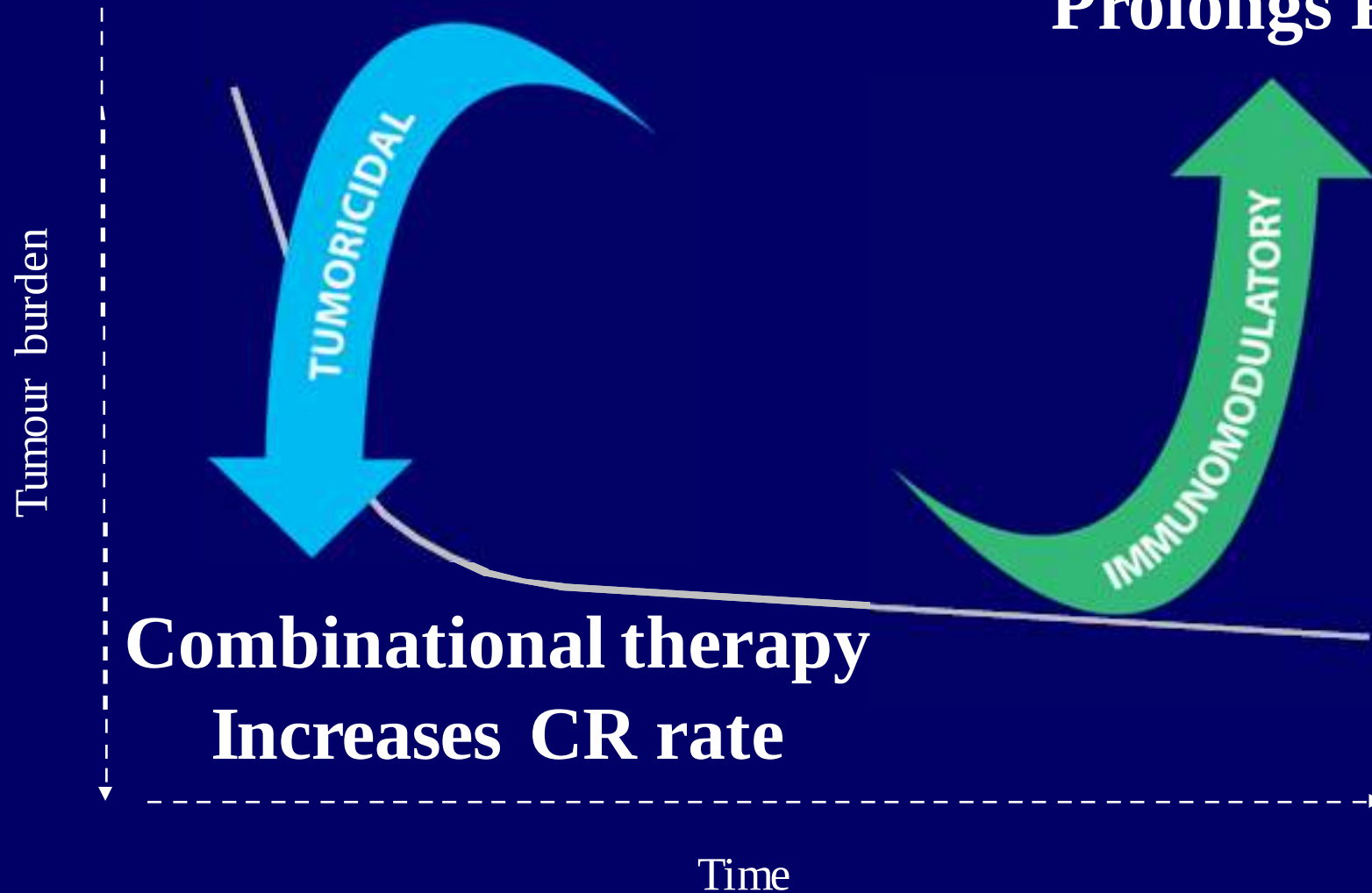
Treatment strategies

Sensitive vs Resistant Disease



Treatment strategy

Continuous therapy
Prolongs PFS

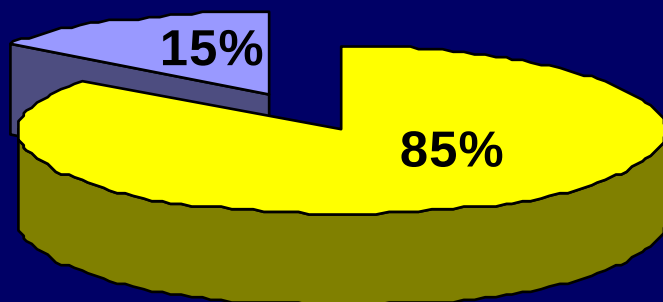


Clinical Impact of VTD Consolidation in VGPR Patients After ASCT

Responses after ASCT

VGPR 85%

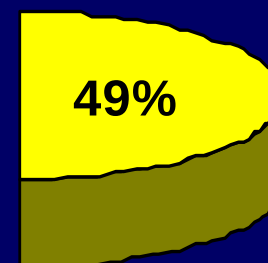
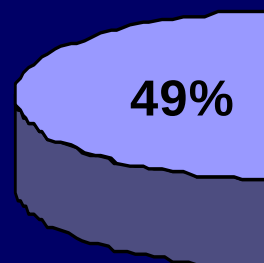
CR 15%



Responses after VTD

VGPR 49%

CR 49%



■ VGPR

■ CR

Complete Response are all the same?

Response Criteria	Tumor gene copy number
Diagnosis	25,000 - 500,000
PR	5,000 – 100,000
VGPR	1,500 – 20,000
Immunofixation-negative CR	1,000 – 10,000
Immunophenotypic CR*	10 – 100
Molecular CR^	5 – 20

**Paiva et al Blood 2009: 114;4369-72; ^Ladetto et al. J Clin Oncol . 2010;28(12):2077-84*

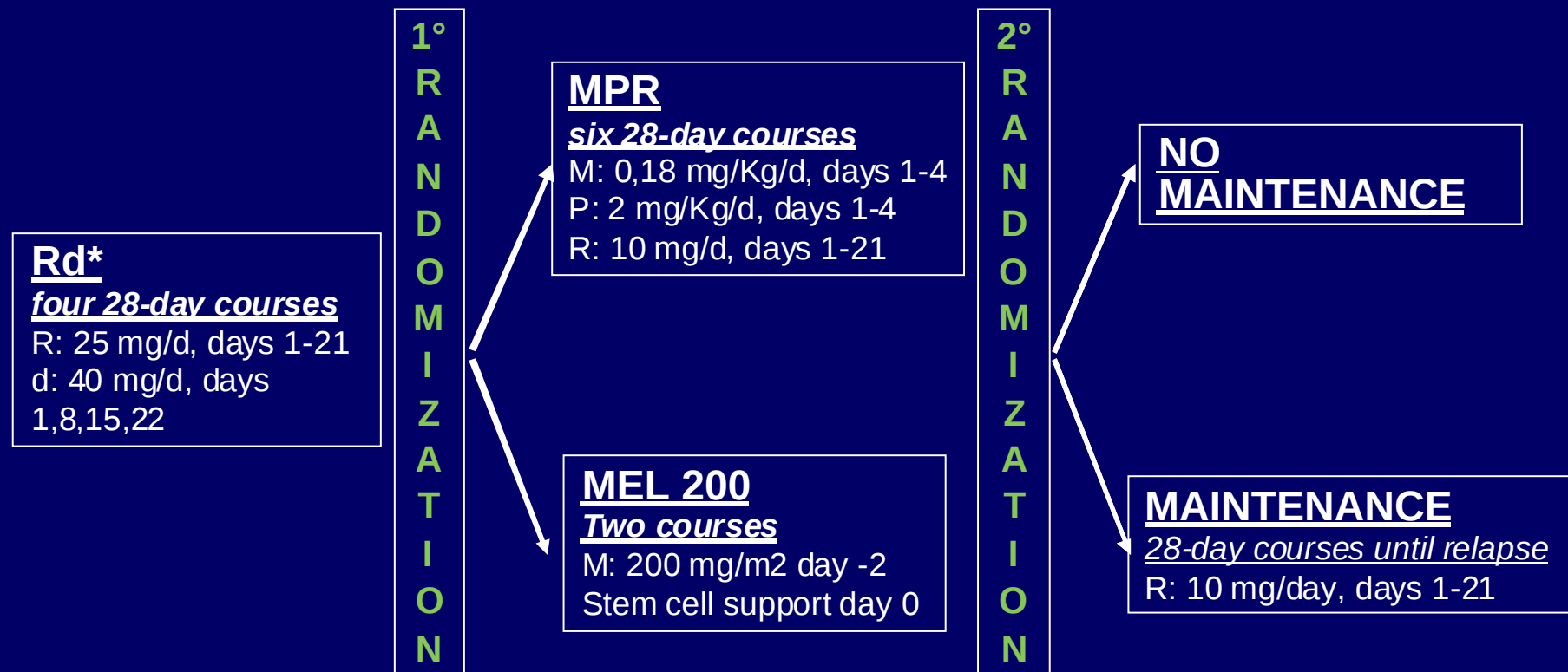
MPR vs MEL200

CRD vs MEL200



Treatment schedule

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

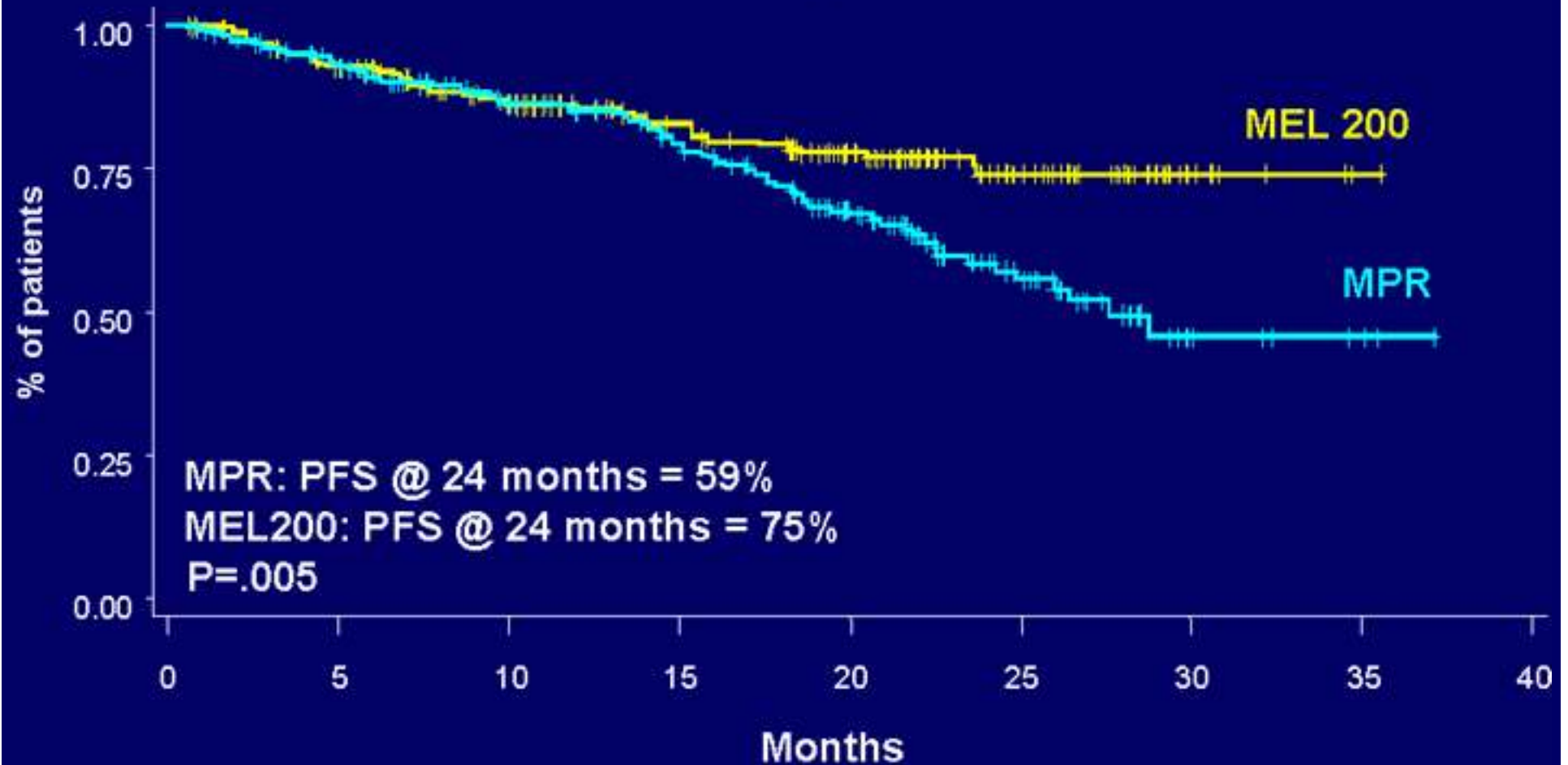


*Thromboprophylaxis randomization: aspirin vs low molecular weight heparin

R, lenalidomide; M, melphalan; d, dexamethasone; P, prednisone

MPR vs MEL200: Progression Free Survival

Median follow-up 20 months



VMPT-T vs VMP

age > 65 years

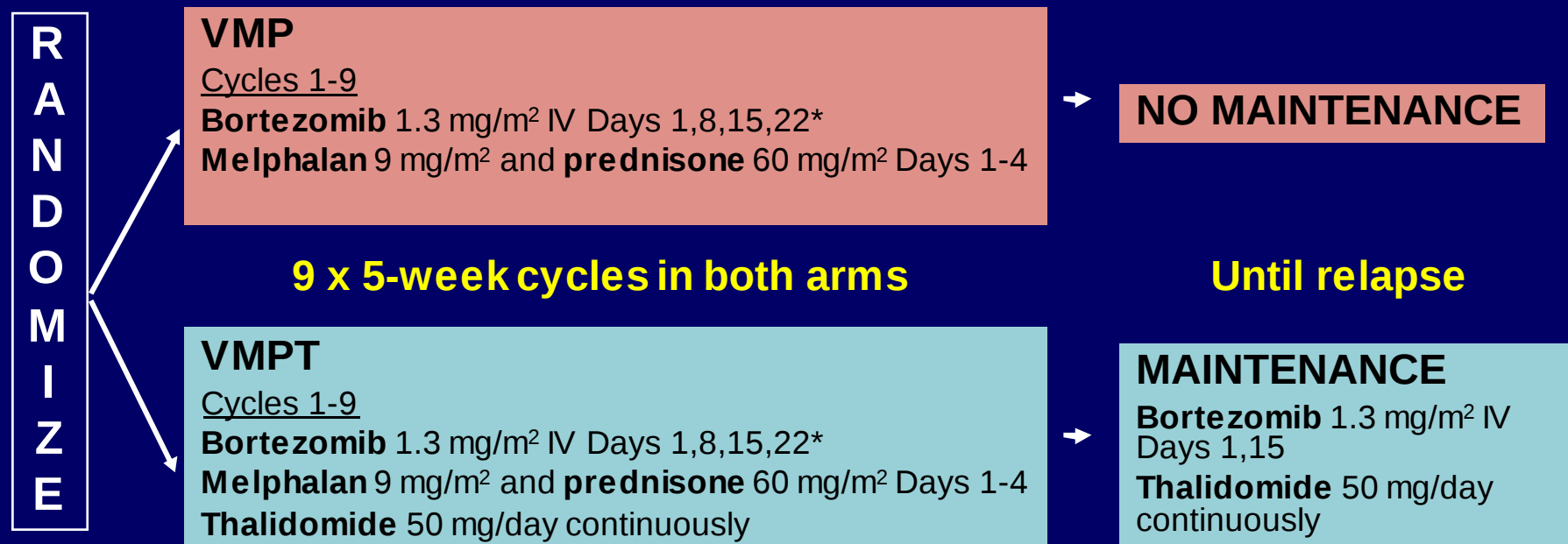


Bortezomib-Melphalan-Prednisone-Thalidomide VMPT-VT vs VMP

511 patients (older than 65 years) randomized from 61 Italian centers

Patients: Symptomatic multiple myeloma/end-organ damage with measurable disease

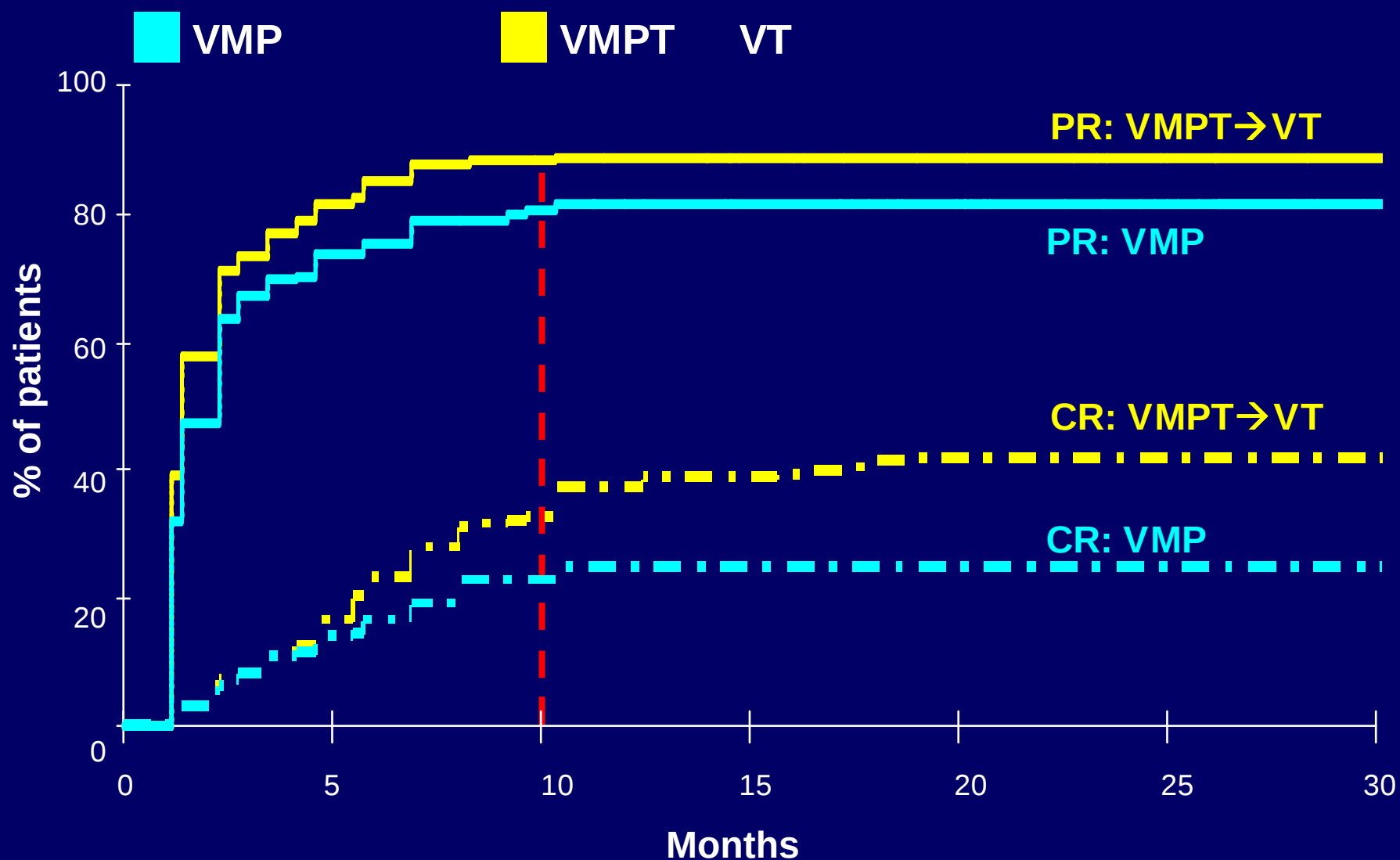
≥ 65 yrs *or* < 65 yrs and not transplant-eligible; creatinine < 2.5 mg/dL



*66 VMP patients and 73 VMPT-VT patients were treated with twice weekly infusions of bortezomib

Bortezomib-Melphalan-Prednisone-Thalidomide

Time to first response and time to CR

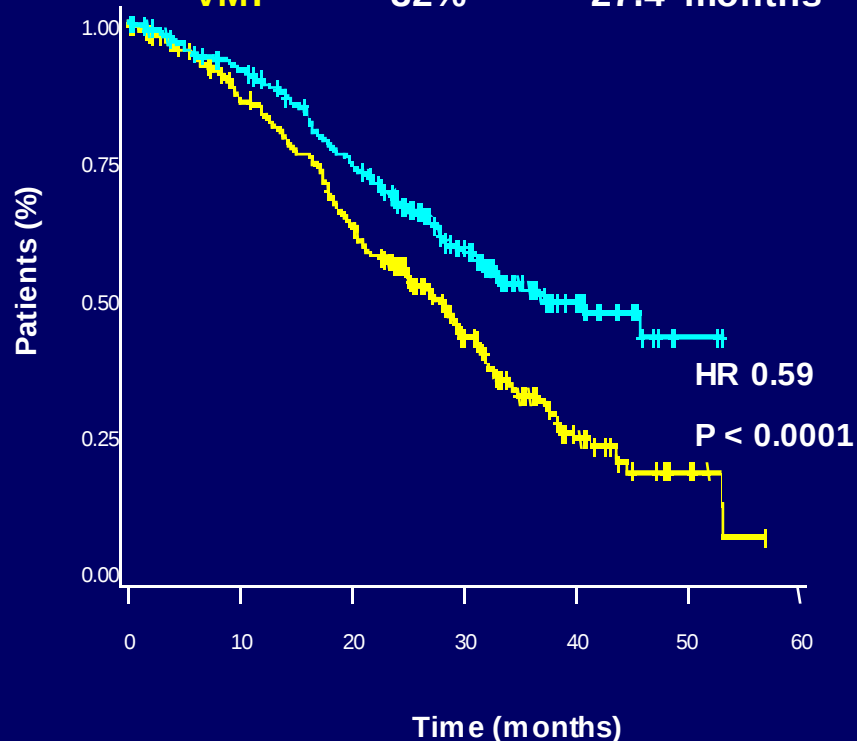


Bortezomib-Melphalan-Prednisone-Thalidomide

Median follow-up 32 months

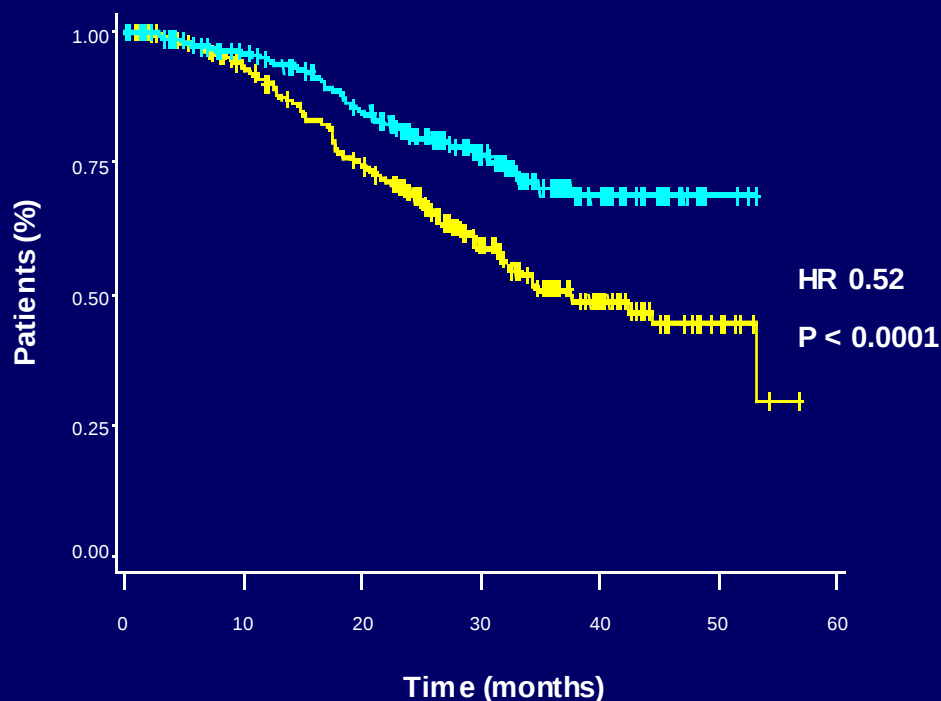
Progression-Free survival
41% Reduced Risk of Progression

	3-years PFS	Median PFS
VMPT	51%	37.2 months
VMP	32%	27.4 months



Time to next therapy
48% Reduced Risk of Progression

	3-years TNT	Median TTNT
VMPT	70%	Not reached
VMP	51%	37.6 months

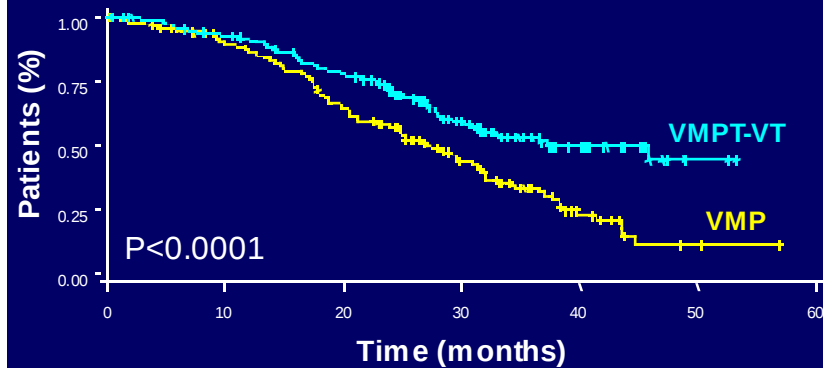


Palumbo A, et al. J Clin Oncol. 2010;Oct 12:[E-pub ahead of print].

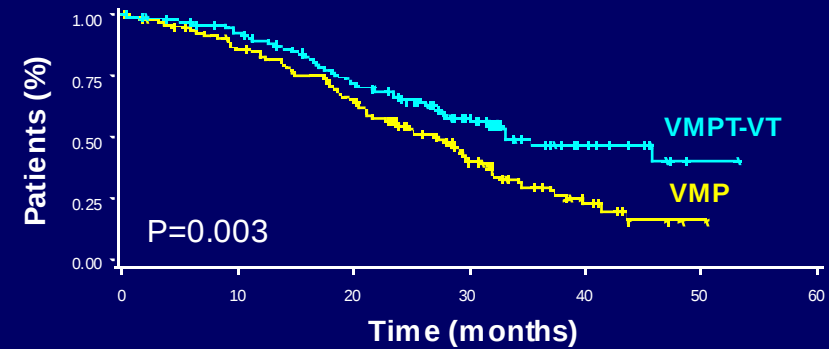
Prognostic factors

PFS according ISS and cytogenetic

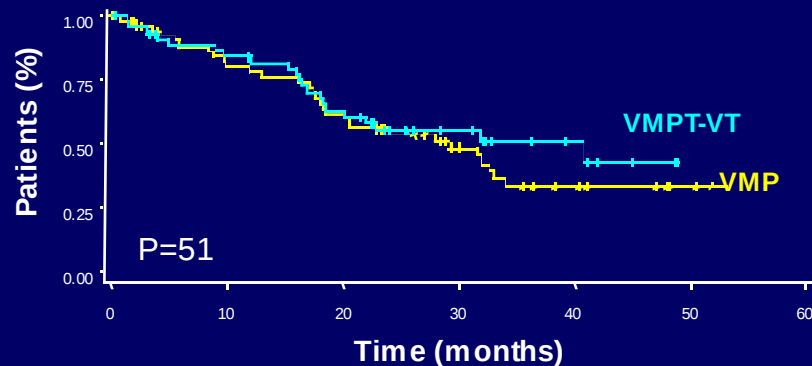
ISS 1 or 2



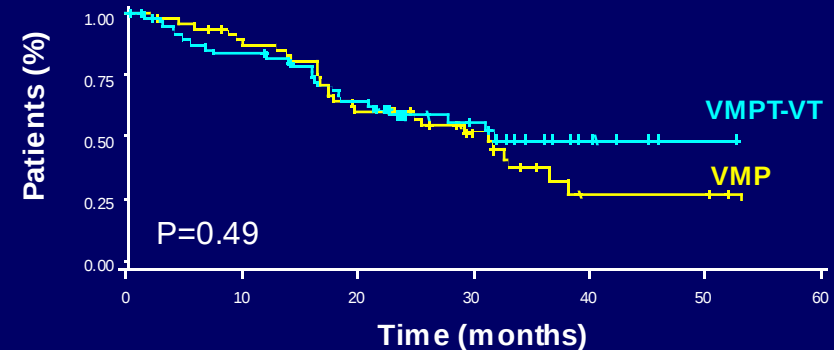
Absence of t(4;14) or t(14;16) or del17



ISS 3



Presence of t(4;14) or t(14;16) or del17



Age-adjusted therapies

Risk stratification

≥ 1 risk factor

Age > 75 years

Cardiac

Pulmonary

Renal

Liver

Grade 3-4 Adverse Event

Risk stratification

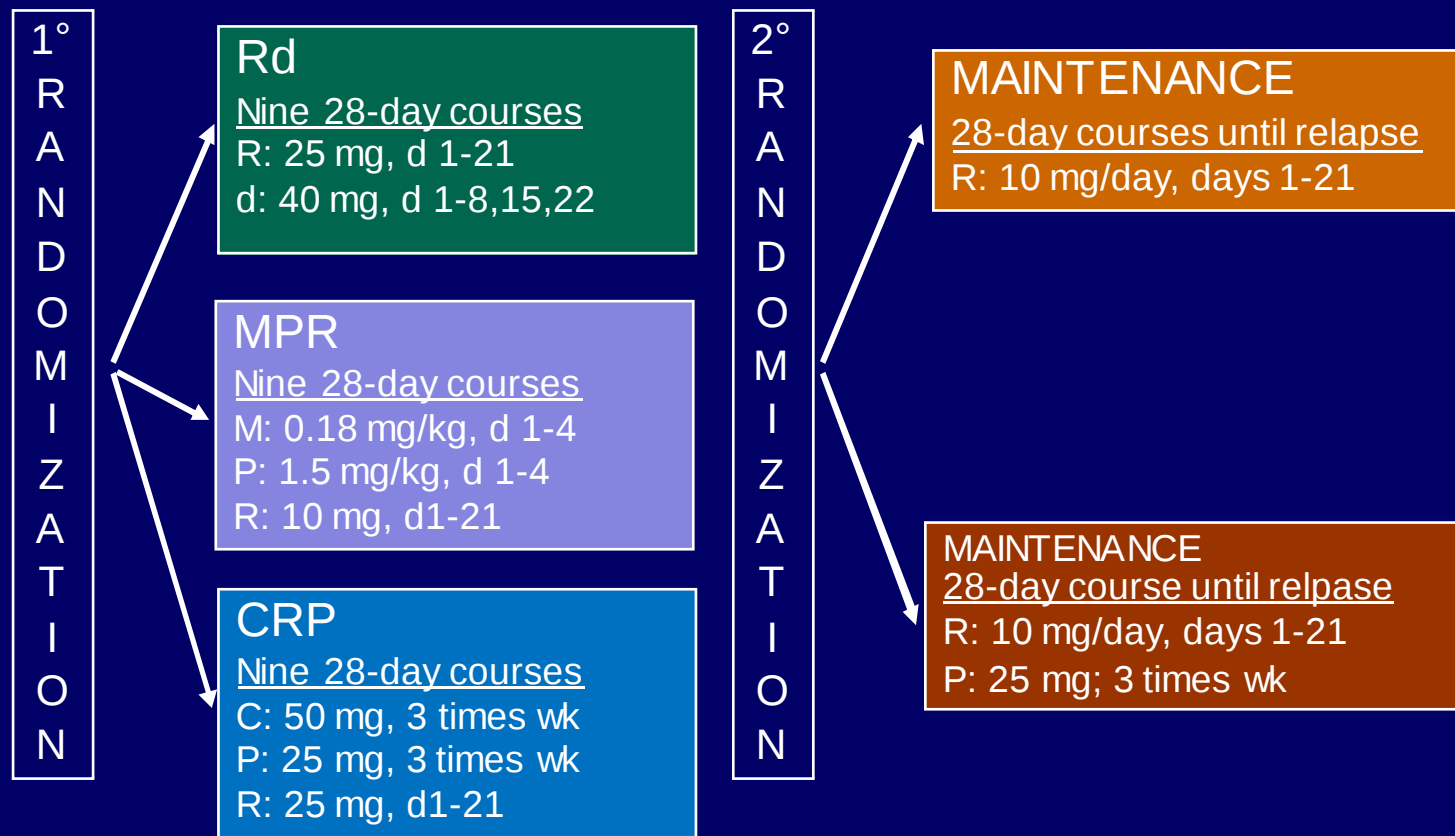
Risk Factors	Action required
• Age over 75 years • Comorbidities: ◦ Cardiac dysfunction ◦ Pulmonary dysfunction ◦ Hepatic dysfunction ◦ Renal dysfunction	 At least one risk factor Reduce to dose level -1  If Grade 3-4 Non-Hemat AE occurs Reduce to dose level -2

Rd vs MPR vs CRP age > 65 years



Treatment schedule

- 650 patients (older than 65 years) randomized from 5 countries
- Patients: Symptomatic disease, organ damage, measurable disease



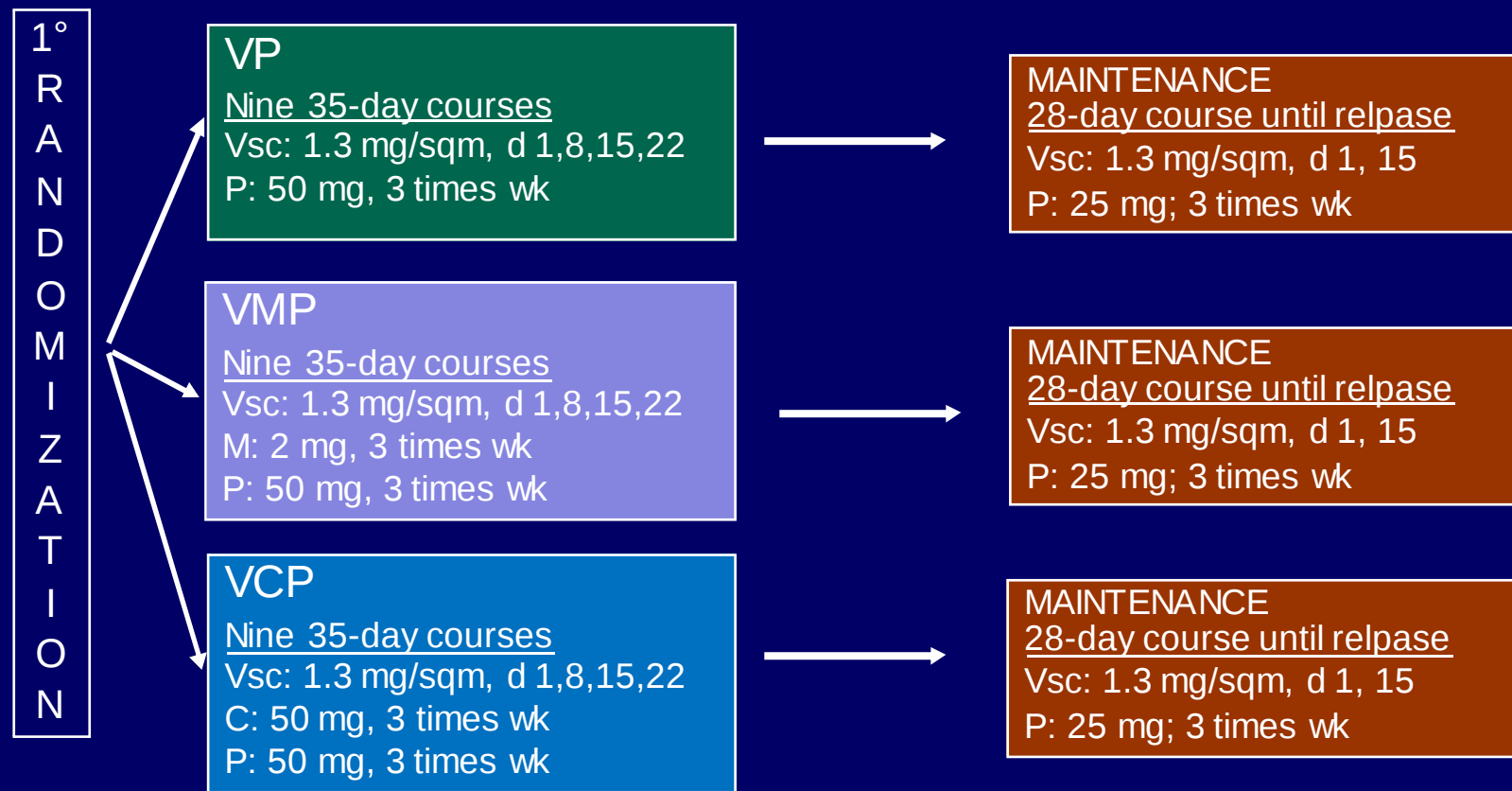
C, cyclophosphamide; R, lenalidomide; M, melphalan; P, prednisone

Subcutaneous VP vs VMP vs VCP age > 75 years



Treatment schedule

- 150 patients (> 75 years) randomized from 3 countries
- Patients: Symptomatic disease, organ damage, measurable disease



Vsc, subcutaneous bortezomib, cyclophosphamide; M, melphalan; P, prednisone

We Are Grateful to All Patients, Nurses and Physicians of the Participating Centers

1. ALESSANDRIA	Levis, Baraldi	39. GENOVA	Carella, Spriano	77. RIMINI	Pasquini, Fattori
2. ANCONA	Leoni, Offidani	40. GENOVA	Bacigalupo, Dominietto	78. RIONERO VULTURE	Musto
3. AOSTA	Di Vito	41. IVREA	Giroto, Aitoro	79. RIETI	Capparella
4. ASCOLI PICENO	Galieni	42. LATINA	De Blasio	80. ROMA	Foà, Petrucci
5. ASTI	Favro, Cravegna	43. LATINA	Cimino	81. ROMA	De Fabritiis, Caravita
6. AVELLINO	Cantore, Volpe	44. LECCE	Di Renzo	82. ROMA	Andriani
7. AVIANO	Tirelli, Rupolo	45. MATERA	Fragasso	83. ROMA	Annino, Bongarzone
8. BARI	Vacca, Ria	46. MESSINA	Brugiatelli	84. ROMA	Leone, De Stefano
9. BARI	Liso	47. MESSINA	Musolino	85. ROMA	Petti, Pisani
10. BELLUNO	Pianezze	48. MILANO	Corradini, Montefusco	86. ROMA	Majolino, De Rosa
11. BENEVENTO	Di Leonardo, Vallone	49. MILANO	Morra	87. ROMA	Amadori
12. BERGAMO	Rambaldi, Galli	50. MILANO	Ciceri	88. ROMA	Avvisati
13. BOLOGNA	Baccarani, Cavo	51. MILANO	Lambertenghi, Baldini	89. ROMA	Recine
14. BOLZANO	Cortellazzo, Pescosta	52. MILANO	Gianni	90. ROZZANO	Santoro, Nozza
15. BRA	Vanni, Stefani	53. MODENA	Marasca	91. S. G. ROTONDO	Cascavilla, Falcone
16. BRESCIA	Rossi, Crippa	54. MODENA	Sacchi	92. SASSARI	Dore, Podda
17. BRESCIA	Russo, Malagola	55. MONZA	Pogliani, Rossini	93. SIENA	Lauria, Gozzetti
18. BRINDISI	Quarta	56. NAPOLI	Pane, Catalano	94. TARANTO	Mazza, Casulli
19. CAGLIARI	Angelucci, Derudas	57. NAPOLI	Ferrara	95. TERNI	Liberati
20. CAGLIARI	La Nasa, Ledda	58. NAPOLI	Mettivier	96. TORINO	Boccadoro
21. CAMPOBASSO	Storti	59. NOCERA INF.	D'Arco, Califano	97. TORINO	Pregno, Benevolo
22. CANDIOLO	Aglietta, Capaldi	60. NOVARA	Gaidano, Rossi	98. TORINO	Tarella, Gottardi
23. CATANIA	Di Raimondo	61. NUORO	Gabbas	99. TREVISO	Gherlinzoni
24. CATANZARO	Peta, Piro	62. ORBASSANO	Saglio, Guglielmelli	100. TRICASE	Pavone
25. CATTOLICA	Pasquini	63. PADOVA	Semenzato, Zambello	101. TRIESTE	De Sabbata
26. CESENA	Guardigni	64. PALERMO	Mirto, Cangialosi	102. UDINE	Fanin, Patriarca
27. CIRE'	Giroto, Freilone	65. PARMA	Rizzoli, Giuliani	103. VENEZIA	Chisesi
28. COSENZA	Morabito	66. PAVIA	Lazzarino, Corso	104. VERBANIA	Montanara, Luraschi
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30. CUNEO	Gallamini, Grasso	68. PESARO	Visani, Leopardi	106. VERONA	Pizzolo, Meneghini
31. FIRENZE	Bosi/Nozzoli	69. PESCARA	Fioritoni, Spadano	107. VICENZA	Rodeghiero, Elise
32. FOGGIA	Capalbo	70. PIACENZA	Cavanna, Lazzaro	108. VITERBO	Montanaro
33. FORLI'	Amadori, Gentilini	71. PINEROLO	Griso	109. ISRAEL	Nagler
34. FROSINONE	Sala	72. PISA	Petrini/Benedetti	110. JERUSALEM	Ben Yehuda
35. GALLARATE	Mozzana, Ciambelli	73. POTENZA	Ricciuti, Vertone	111. KEFAR SABAH	Manor
36. GENOVA	Gobbi, Canepa	74. RAVENNA	Zaccaria, Cellini	112. ZERIFIM	Komberg
37. FORLI'	Amadori, Gentilini	75. REGGIO CALABRIA	Noble, Callea	113. HAIFA	Attias
38. GENOVA	Gobbi, Canepa	76. REGGIO EMILIA	Gugliotta, Masini		