

Newly Diagnosed Myeloma <65 years: Facts and Questions

EMN-PETHEMA/GEM

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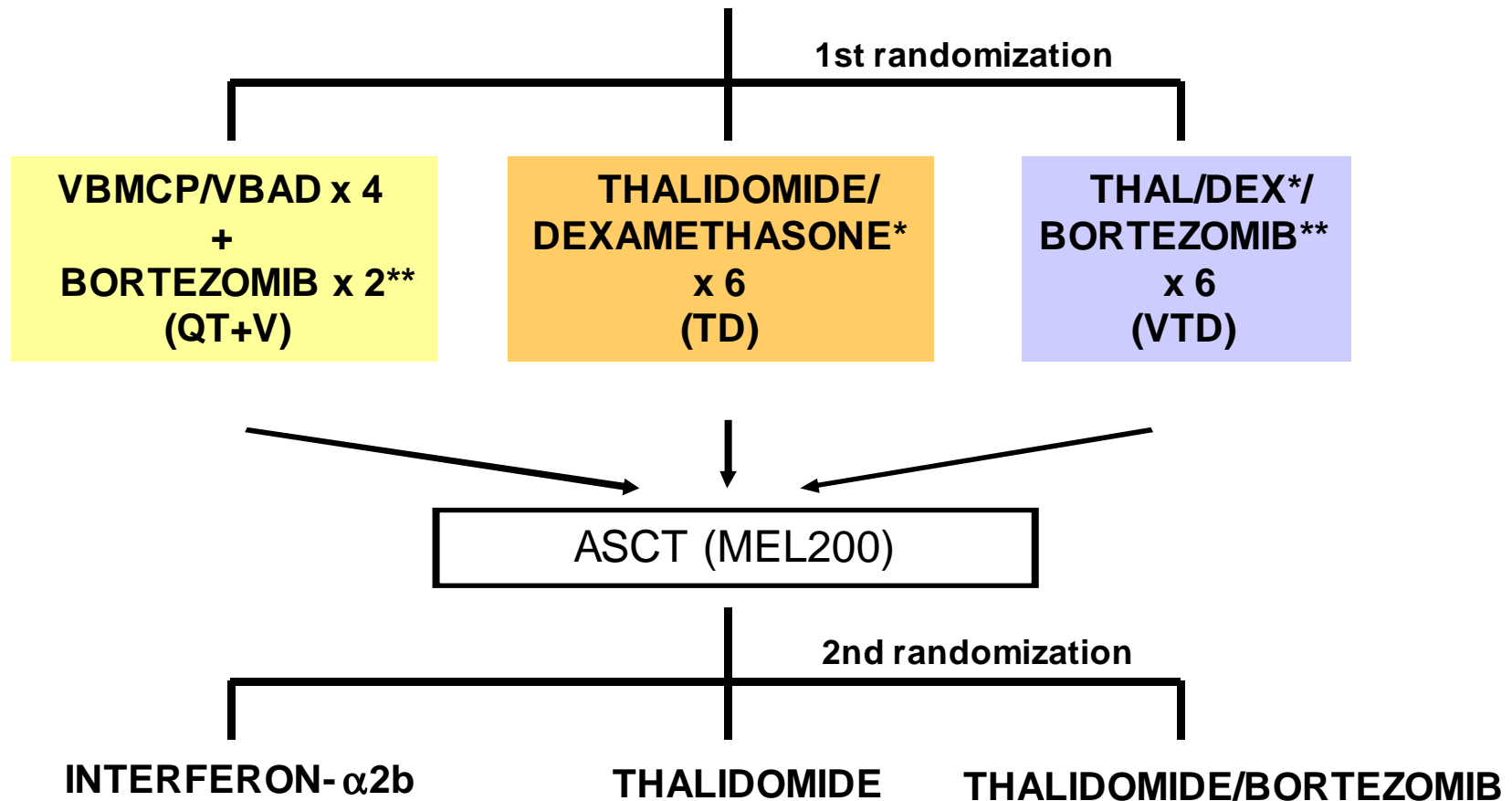
On Behalf of PETHEMA/Spanish Myeloma Group

Paris, May 4, 2011



GEM05MENOS65

De “**nov**o” symptomatic MM <65 yrs



*Thalidomide: 200 mg/day; Dexamethasone: 40 mg on days 1-4, 9-12

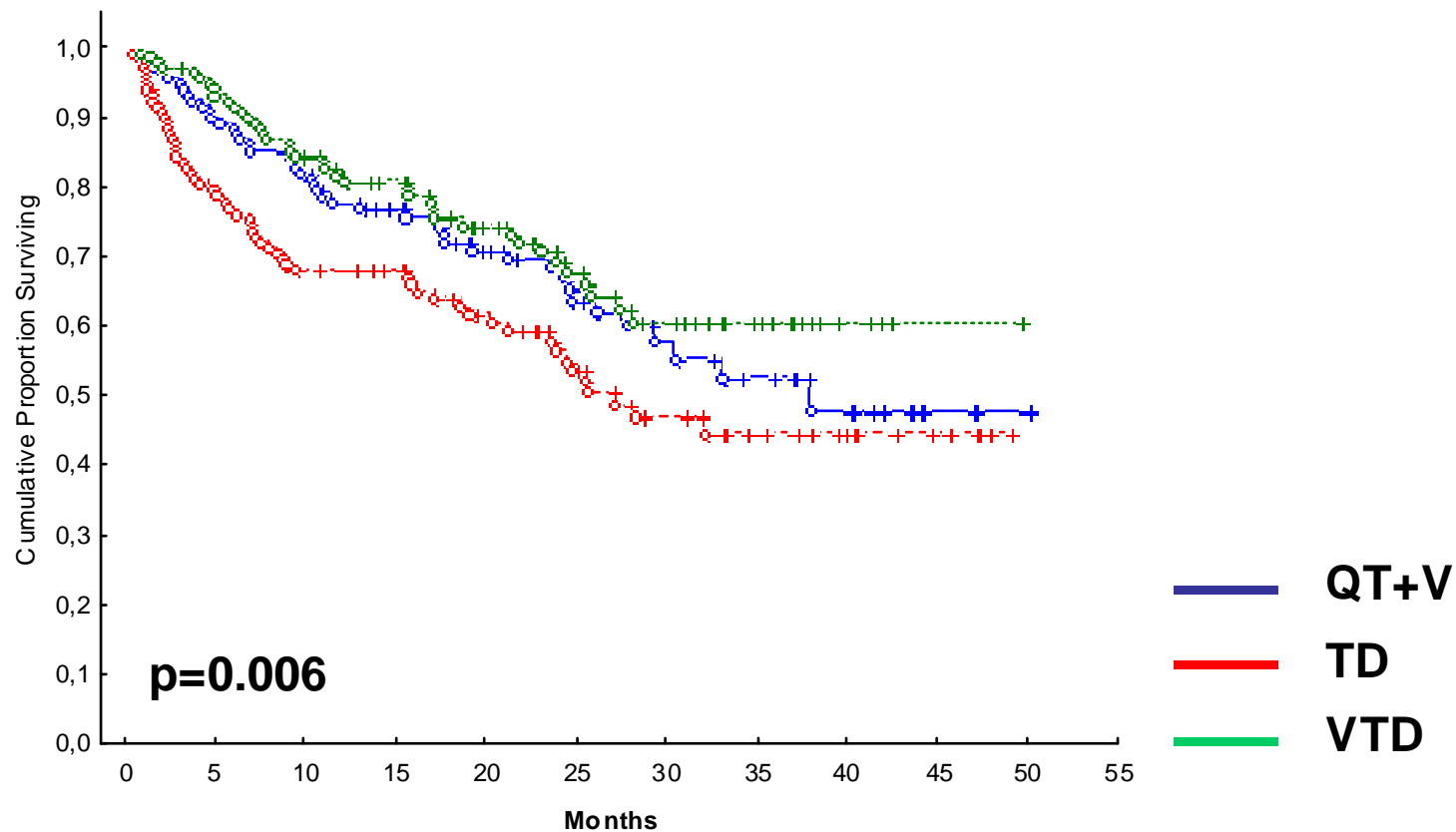
**Bortezomib: 1.3 mg/m² on days 1,4,8, and 11

TD and VTD at 4 week-interval

Pre- and post-ASCT **CR** according to the induction regimen

	Pre-ASCT (%)	Post-ASCT (%)
QT+V	21	38
TD	14	24
VTD	35	46

PFS according to the induction arm



Median follow-up: 27 months

Current asked questions

1. Number of induction cycles?
2. Progression on induction: still an issue?
3. Best therapy for extramedullary disease?
4. Can novel agents overcome high-risk cytogenetics?

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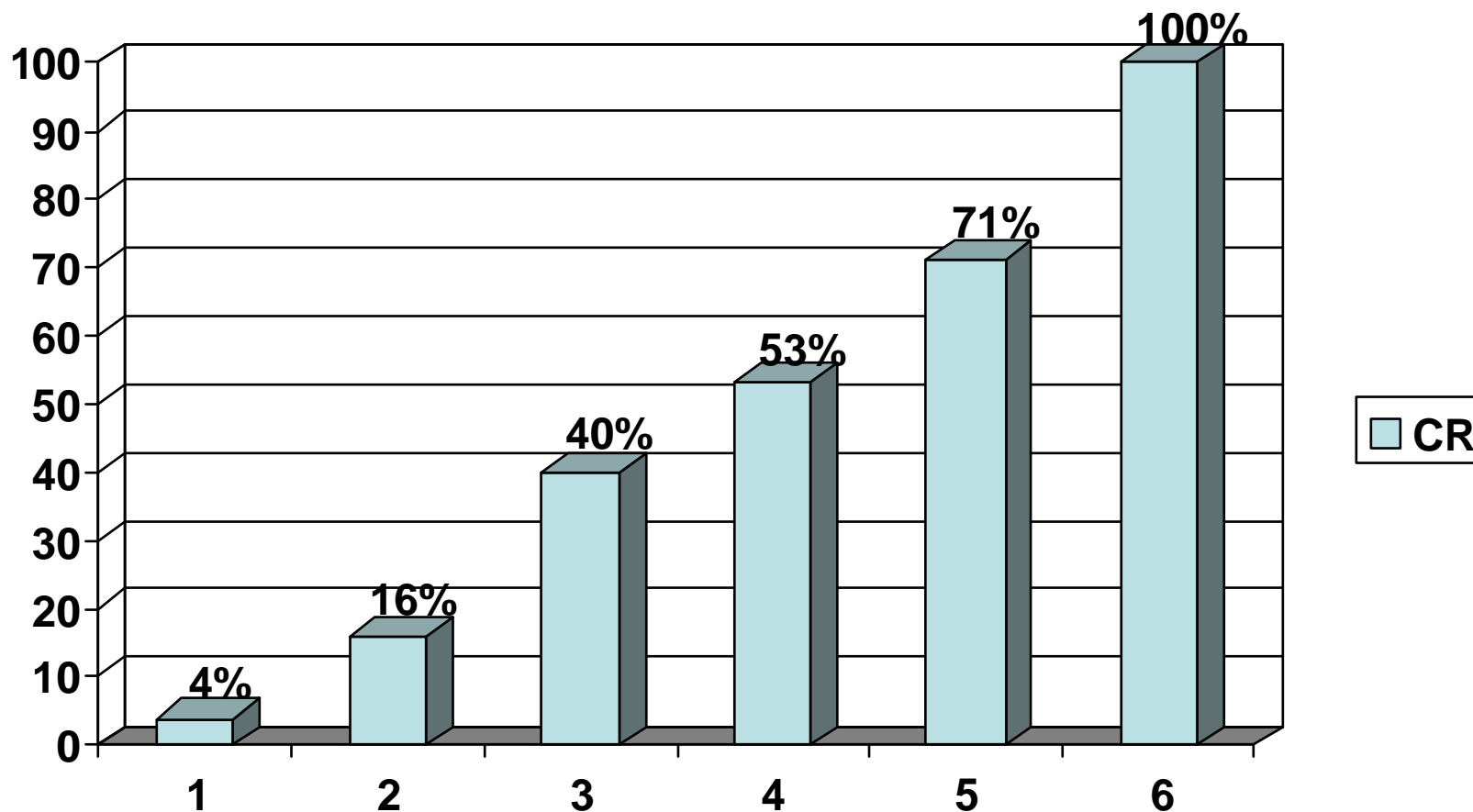
Response rate with **VTD** according to the **number** of cycles

Trial	Nº cycles	CR (%)
GIMEMA ¹	3	19%
PETHEMA/GEM ²	6	35%

¹Cavo et al, The Lancet 2010;376:2075-2085

²Rosiñol et al, Blood 2010;116:139 (abstract 307)

CR rate over induction (in patients who achieved CR)



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Progression disease with induction

	QT+V (n=129)	TD (n=127)	VTD (n=130)
CR (%)	21*	14*	35*
VGPR (%)	15	15	25
PR (%)	39	33	25
SD (%)	12	12	6
PD (%)	12 [#]	23	7 ^{&}
Early deaths (%)	1	1	2

*VTD vs QT+V, $p=0.01$; VTD vs TD, $p=0.0001$

[#]QT+V vs TD, $p=0.02$

[&]VTD vs TD, $p=0.0004$

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Response in patients with **extramedullary** plasmacytomas (EMP)

	QT+V (n=17)	TD (n=23)	VTD (n=26)
CR (%)	29	14*	42*
VGPR (%)	12	8	12
PR (%)	35	22	26
SD (%)	-	12	4
PD (%)	24	40**	12**
Early death (%)	-	-	4

*p=0.02 **p=0.02

Progressive disease in patients with and without EMP

24% vs. 11%, $p=0.01$

	QT+V (n=17)	TD (n=23)	VTD (n=26)
EMP (%)	24	40*	12*
No EMP (%)	9	19	6

* $p=0.02$

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Response in patients with **high-risk** cytogenetics: t(4;14); t(14;16); del (17p)

	QT+V (n=23)	TD (n=22)	VTD (n=23)
CR (%)	22*	-*	35*
VGPR (%)	9	27	22
PR (%)	30	18	22
SD (%)	13	14	9
PD (%)	26**	41**	3**
Early death (%)	-	-	9

*VTD vs TD, p=0.002; VTD vs QT+V, p=0.02

**VTD vs TD, p=0.004; VTD vs QT+V, p=0.04

CR rate according to cytogenetics and induction arm

	QT+V (n=16)	TD (n=16)	VTD (n=13)
t(4;14)(%)	25	-	38

*VTD vs TD, $p=0.01$; VTD vs QT+V, $p=0.05$

	QT+V (n=8)	TD (n=7)	VTD (n=7)
Del (17p)(%)	-	-	58*

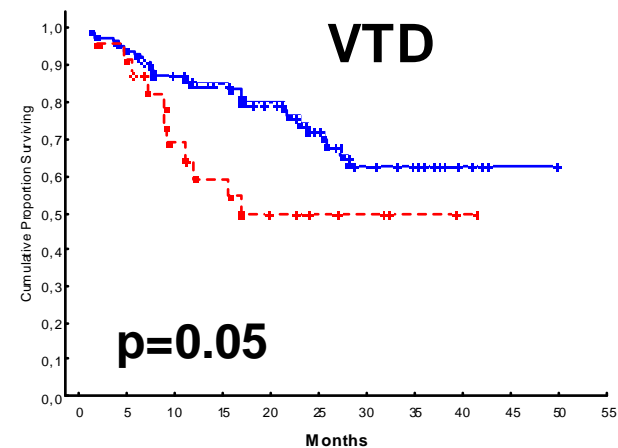
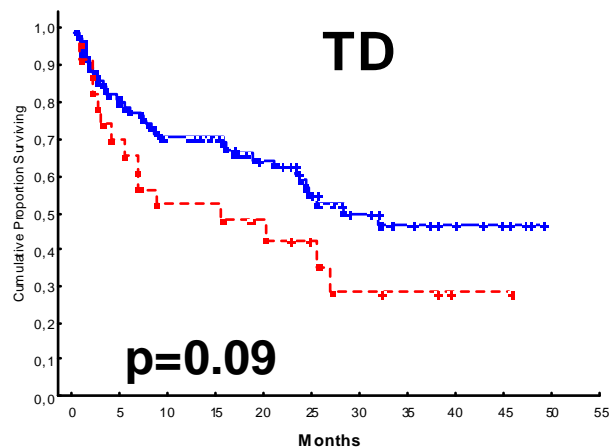
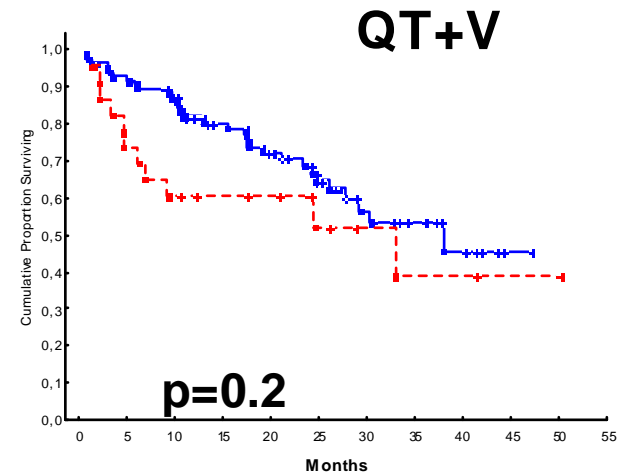
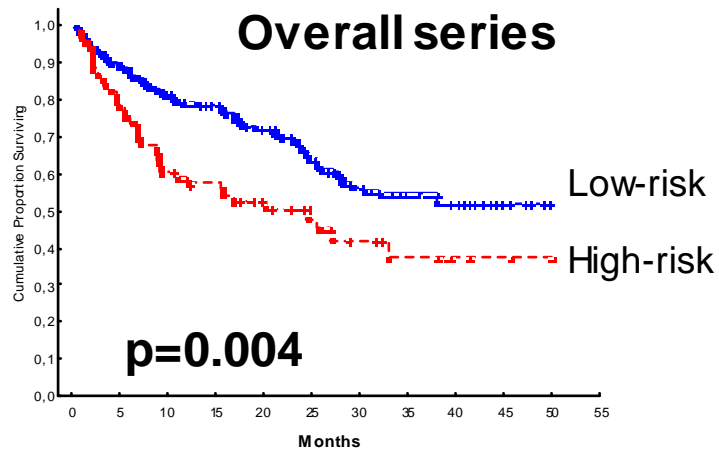
* $p=0.03$

CR rate in patients with and without **t(11;14)**

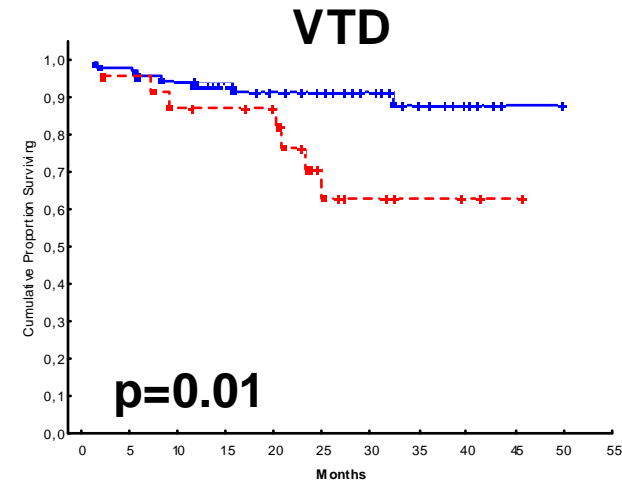
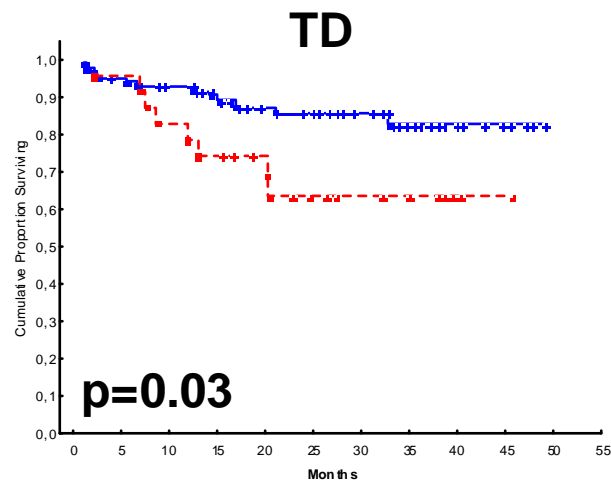
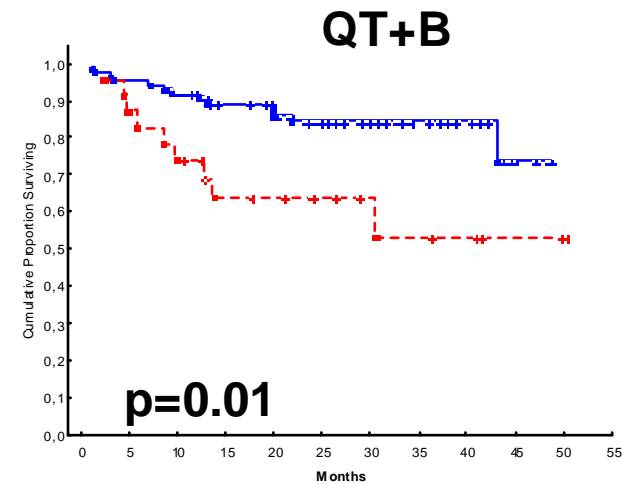
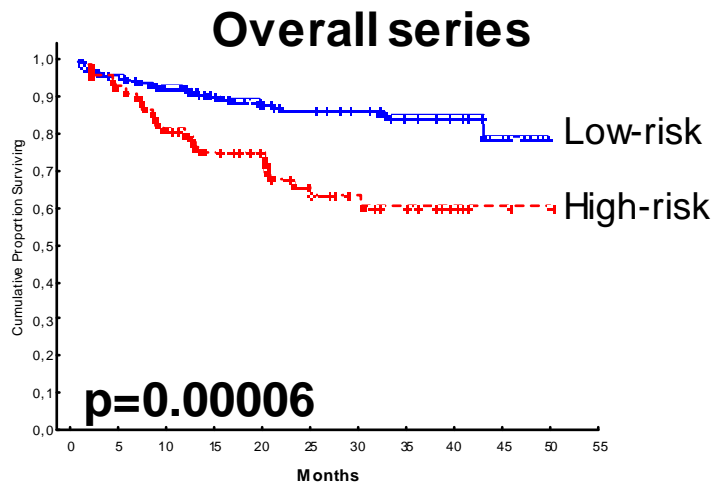
11% vs. 27%; p=0.01

	QT+V (n=16)	TD (n=22)	VTD (n=16)
t(11;14) (+)	18%	4%	12%
t(11;14) (-)	24%	16%	40%

PFS in patients with low and high-risk cytogenetics according to the treatment arm



OS in patients with low and high-risk cytogenetics according to the treatment arm

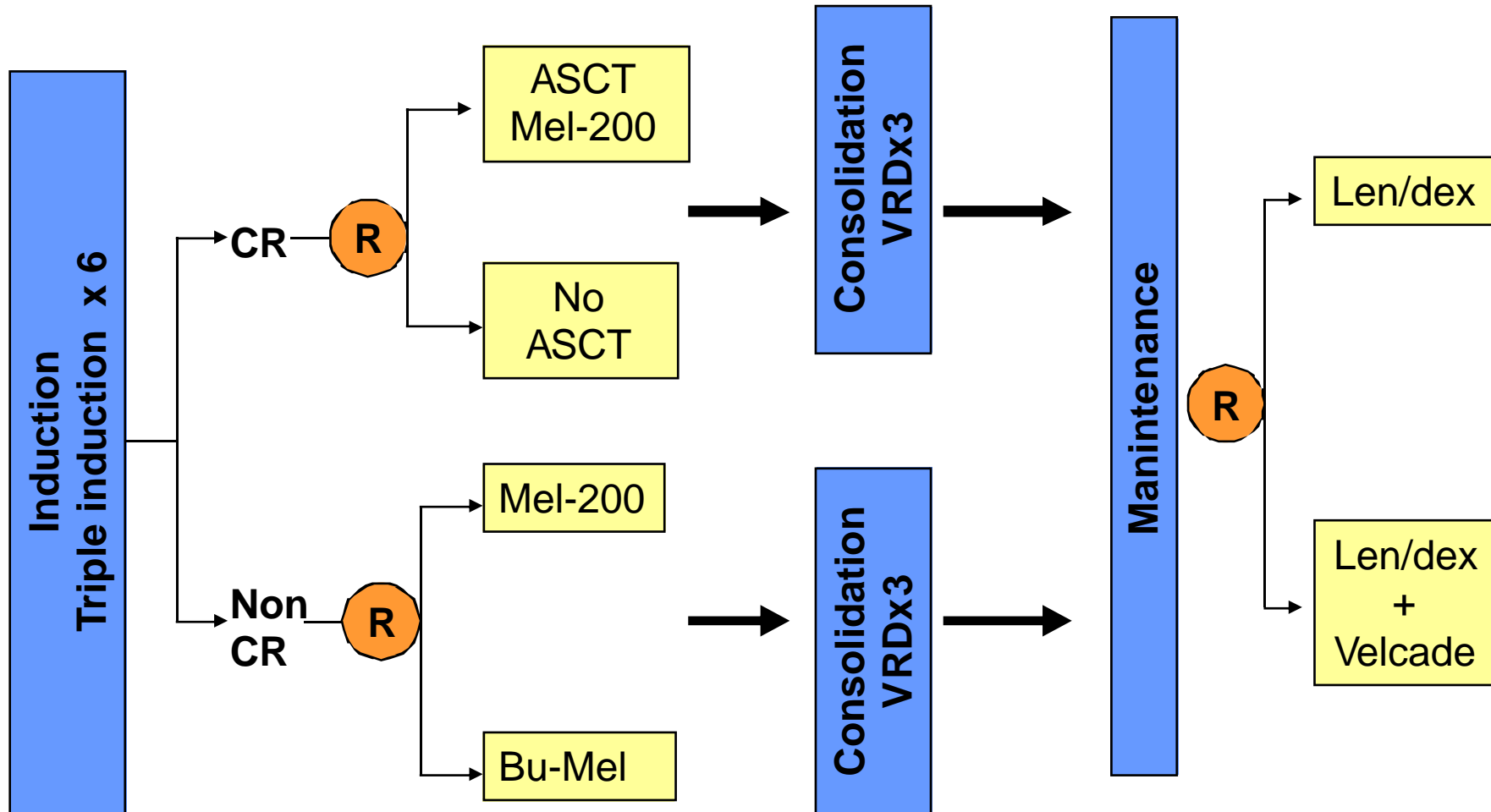




And, what about the future?

More questions...

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Messi



Pedro



Villa



Acknowledgments



The investigators of the Spanish Myeloma trials!