

Lenalidomide/melphalan/dexamethasone in newly diagnosed patients with immunoglobulin light chain amyloidosis: results of a prospective phase 2 study with long-term follow up

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Received: December 24, 2016.

Accepted: May 9, 2017.

Pre-published: May 18, 2017.

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Variable	Hematological remission (CR+VGPR)		Overall Survival (OS)		Event free Survival (hemEFS)	
	OR [95 % CI]	p-value	HR [95 % CI]	p-value	HR [95 % CI]	p-value
Age (10 year increase)	1.16 [0.62 – 2.18]	0.64	0.79 [0.56 – 1.12]	0.19	0.86 [0.57 – 1.29]	0.46
Sex (female vs male)	0.61 [0.23 – 1.61]	0.32	1.06 [0.56 – 2.04]	0.85	0.66 [0.37 – 1.17]	0.15
Treatment (L-M-dex vs M-Dex)	2.80 [1.12 – 6.98]	0.03	0.62 [0.33 – 1.17]	0.14	0.64 [0.38 – 1.05]	0.08
Light chain (lambda vs. kappa)	2.36 [0.52 – 10.61]	0.26	0.50 [0.21 – 1.23]	0.13	0.48 [0.24 – 0.93]	0.03
Cardiac Mayo Score (3 vs 1+2)	0.22 [0.07 – 0.67]	0.01	2.68 [1.34 – 5.35]	0.005	4.00 [2.26 – 7.05]	<0.001
dFLC (2-fold change)	1.08 [0.85 – 1.37]	0.53	1.23 [1.02 – 1.50]	0.03	0.99 [0.87 – 1.12]	0.85
Number of organs involved	1.08 [0.57 – 2.04]	0.82	1.35 [0.89 – 2.06]	0.16	1.15 [0.84 – 1.56]	0.38

Supplement Table 1: Multivariable analysis of hemR (CR+VGPR), OS and EFS comparing L-M-dex vs. M-Dex.

Abbreviations: OR odds ratio, HR hazard ratio, CI confidence intervals. For number of organs involved we compared three categories, 1 vs. 2 vs. ≥ 3 .

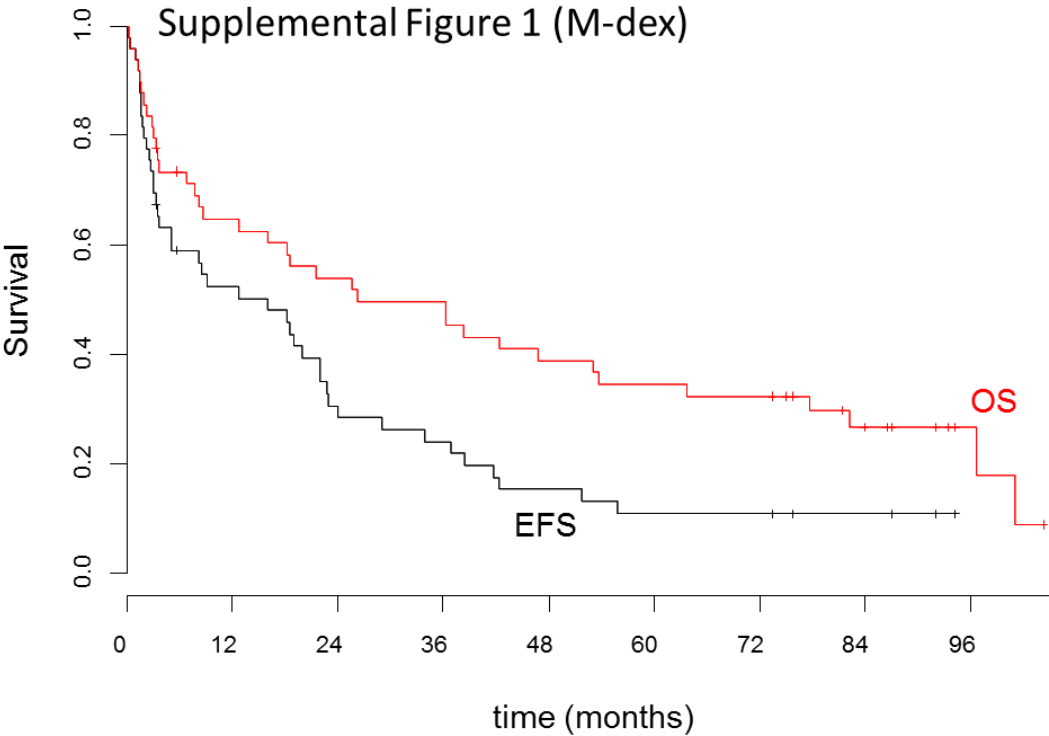
Supplemental Table 2: Patient characteristics for the historical control group (M-Dex)

Patient cohort	M-Dex
Age, years, median (range)	65.6 (45-74)
Sex: Female Male	22 27
Monoclonal light chain, number of patients: Kappa Lambda	9 40
Absolute involved free light chain concentration, mg/l, median (range): Kappa Lambda dFLC	206 (0 - 1.037)
Plasma cell content of the bone marrow, median % (range)	12 (2-42)
Number of organs involved, number of patients: 1 organ 2 organs ≥ 3 organs	8 16 25
Dominant organ, number of patients*: Heart Liver Gut Kidney Peripheral Nerves Other	27 3 4 12 1 6
NT-proBNP, ng/l, median (range)	3.878 (102 - 22.711)
cTNT (ug/l), median (range)	0.0 (0-0.5)
Cardiac involvement, number of patients	41
Mayo staging system, number of patients: 1 2 3	7 20 22
Creatinine clearance, ml/min, median (range)	67 (42-239)
Dex dosage in (mg) of first cycle, median (range)	40 (20-40)

*patients might have several dominant organ involvements, therefore the sum of patients is larger than 49.

Abbr.: N-terminal prohormone of brain natriuretic peptide (NT-proBNP), cardiac troponin T (cTNT).

Supplemental Figure 1: Estimated EFS and OS in the historical M-Dex group



49	24	13	11	7	5	5	3		EFS
49	30	25	23	18	16	15	9	3	OS