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Autologous stem cell transplantation for newly diagnosed multiple myeloma - real-world data from 2,149 Czech patients

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Running head: Autologous Transplant for Newly Diagnosed Myeloma

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Author Contributions

TP and RH designed the study and wrote the manuscript. LePo performed the statistical analysis. LuPo, IS, JR, JM, TJ, MK, VM, DZ contributed substantially to discussion of the content. All authors critically reviewed the manuscript and approved the final manuscript for publication.

Data Sharing Statement

The datasets analyzed during the current study are available from the corresponding author on reasonable request.

High-dose therapy followed by autologous hematopoietic stem cell transplantation (HDT/ASCT) has been the centerpiece of multiple myeloma treatment and plays an important role in the first-line therapy, even in the era of novel drugs enriched by monoclonal antibodies, which has been repeatedly confirmed by prospective randomized trials. However, real-world evidence has been playing an important role. Therefore, using the Registry of Monoclonal Gammopathies (RMG), we conducted a retrospective study to provide an overview of the characteristics of transplant-eligible patients and the effectiveness of first-line treatment. The study was conducted in accordance with the principles of the Declaration of Helsinki. The analysis was approved by the RMG review board. Patients gave their informed consent for inclusion into the registry.

A total of 2,149 newly diagnosed multiple myeloma patients (NDMM) who underwent single or tandem HDT/ASCT (treated between 1995 and 2020) were included in the analysis. The proportion of patients undergoing HDT/ASCT has been fluctuating around 33% within the last 20 years (Supplementary Figure 1). The median age was 59 years (42-68). The International Staging System was I/II/III in 45%/31%/24% of patients. The results of fluorescence in situ hybridization (FISH) testing were available in 35% (746/2,149) of cases. The cohort spans a long period, and earlier patients were more likely to have unknown cytogenetic status. However, the two cohorts (known vs. unknown FISH) differ in age, ISS, PFS and OS ($p < 0.001$). The observed differences likely reflect the fact that more aggressive disease typically yields higher proliferation, making FISH analysis easier to obtain valid results.

High-risk cytogenetic features defined by IMWG [del(17p) and/or t(4;14) and/or t(14;16)] were found in 32.6% (243/746) of cases (Table 1). The combination of agents used in the induction regimen included a proteasome inhibitor (PI), an immunomodulatory drug (IMiD) and a

glucocorticoid (GC) in 29.4% (631/2,149) of patients; PI, GC and chemotherapy (CHT) in 24.4% (525/2,149); GC and CHT in 22.6% (486/2,149) and IMiD, GC and CHT in 15.6% (336/2,149).

In the Czech Republic, the combination of bortezomib, thalidomide and dexamethasone (VTD) as an induction regimen was the standard of care (SOC) from 2016 until late 2025. In the past, cyclophosphamide, bortezomib and dexamethasone (CVD) or cyclophosphamide, thalidomide and dexamethasone were frequently used in induction treatment. Monoclonal antibodies played just a marginal role at the analyzed period - 0.5% (10/2,149). Consolidation therapy was given in 3.4% (73/2,149) of patients. In 16.9% (363/2,149) of patients, maintenance was administered, lenalidomide in 43.8% (159/363) of the cases. The median length of maintenance treatment was 12 (6.0, 25.3) months. Tandem HDT/ASCT was given to 12.5% (268/2,149) of patients. Disease status at the time of HDT/ASCT was defined as a stringent complete response (sCR) in 1.8% (32/1,760) of patients, complete response (CR) in 11.3% (199/1,760), very good partial response (VGPR) in 39.1% (689/1,760), partial response (PR) in 40.8% (718/1,760), minimal response (MR) in 3.8%, (66/1,760), stable disease (SD) in 2.4% (42/1,760), and not available in 18.8% (403/2,149). The overall response rate (ORR) on day 100 after HDT/ASCT was 93.1%, VGPR and better was reached by 68% of patients (sCR: 10.3% [210/2,035], CR: 22% [447/2,035], VGPR: 35.7% [726/2,035], PR: 25.2% [512/2,035], MR: 2.6% [53/2,035], SD: 1.3% [27/2,035], PD: 2.9% [60/2,035]). Taking all together, ORR was not improved when comparing the post-induction with post-transplantation period but there was a clear improvement in the depth of response (CR+sCR 13.1% vs. 32.3%).

After a median follow-up of 56.3 months, the median overall survival (mOS) and the median progression-free survival (mPFS) was 97.0 (92.8-105) and 35.5 (34-37.7) months,

respectively (Figure 1A, 2A, Supplementary Table 2), almost identical results as in a large global real-world study published in 2024 (mOS 90.2 months [88.2–93.6]; mPFS 36.5 months [36.1-37.0])¹. There was no statistically significant difference in survival of patients who initiated treatment between 2005-2009 and 2010-2014: mOS 98.4 vs. 89.2 months (p=0.089); mPFS 32.7 vs. 33.6 (p=0.989) months. The transplant-related mortality was equal to 0.7% (16/2,141).

Age was shown to be a prognostic marker for overall survival – mOS for <49, (50-59), (60-69) and >70-year-olds was 134.7, 100.7, 87.6 and 43.0 months, respectively (p<0.001) (Figure 1B). Nevertheless, the proportion of patients older than 70 was limited (27/2,149) and should be interpreted with caution. There was no statistical difference in the survival of patients aged 61-64 and 66-69 – mOS 86.9 vs. 90.1 months (p=0.711) (Figure 1C). Patients responding with CR after transplantation achieved better OS– mOS was 132.3, 87.6 and 90.4 months for CR+sCR, VGPR, PR and worse, respectively (p<0.001) (Figure 1D). The difference in PFS in favor of tandem transplantation did reach statistical significance – mPFS 47.3 vs. 34.8 months (p=0.003) (Figure 2D). Our data did not show a significant improvement in PFS when tandem transplantation was used for patients with high cytogenetic risk compared to a single transplantation - mPFS 30.9 vs. 24.7 months (p=0.158) (Figure 2E). The use of maintenance was associated with improved OS (median 106.9 vs. 88.4 months, p=0.008) and PFS (median 38 vs. 26.6 months, p<0.001) (Figure 1F, 2F). In the multivariable analysis including cytogenetic risk, age, ISS, Durie-Salmon stage and ECOG, the high-risk cytogenetics (OS and PFS), age >60 years (OS and PFS) and Durie-Salmon stage III (PFS) were independently associated with inferior prognosis (Supplementary Table 1).

Even in the era of novel drugs, HDT/ASCT has repeatedly proved its role in treatment of fit NDMM patients in randomized clinical trials ^{2,3}. The percentage of patients undergoing

HDT/ASCT in the Czech Republic is comparable to the Finnish real-world study presenting 30% of NDMM in 2015 ⁴. High-dose therapy with autologous stem cell transplantation used to be considered exclusively in patients under the age of 65 but has proved itself to be safe and efficient even for patients over this age ⁵. The European Society for Blood and Marrow Transplantation registered an increasing use of HDT/ASCT in the first-line treatment of elderly patients, particularly in the 65-69 age group ⁶ and a more recent analysis of the Center for International Blood and Marrow Transplant Research confirmed this trend by showing almost a 2-fold increase in HDT/ASCT use among NDMM patients aged ≥ 70 years in 2017 compared to 2013 ⁷. Consequently, the latest EHA-EMN guidelines recommend HDT/ASCT for patients under the age of 70. Our analysis confirmed this approach by showing no difference in survival between the age groups of 60-64 and 65-69. The \geq CR rate on day 100 after transplantation was 32%, which is inferior to the data of an Argentinean study that assessed 322 NDMM patients who received a combination of VTD (26%) or CVD (74%) as induction and the CR rate was 49% and 40%, respectively ⁸. In contrast, the ORR of 93.1% in our cohort is superior to the Finnish patients treated with bortezomib based induction (ORR 86.9%). The median PFS and OS for our cohort were 35.5 and 97.0 months, respectively, which is considered satisfying in the real world but cannot be compared to clinical trials, indeed- GIMEMA-MMY-3006: CR 48.7%, mPFS 57 months, 10-year OS 60% ⁹; CASSIOPEIA: \geq CR 26%, mPFS 52.8 months ¹⁰. However, both studies used consolidation, most of the patients received maintenance, and solely patients < 65 years were eligible. Similarly to our results, 10.1% of upfront HDT/ASCT reported in Europe between 2013 and 2017 were tandem ¹. The relevance of tandem HDT/ASCT in first line continues to be debated due to nonuniform outcomes from randomized trials and meta-analyses, moreover real-world data are rarely published. In the contemporary setting of a quadruplet being SOC for treatment of newly diagnosed transplant-eligible patients, a phase 2 study 2018-04 showed

that daratumumab plus carfilzomib, lenalidomide and dexamethasone (KRD) with tandem transplant had led to pre-maintenance ORR and MRD negativity rate of 100% and 94%, respectively and to 30-month PFS and OS of 80% and 91%, respectively ¹¹. In the MIDAS trial, no statistically significant difference in the pre-maintenance MRD-negative status was found between MRD-positive patients consolidated by tandem or by single transplantation followed by 2 cycles of IsaKRD ¹². The IMWG recommends the use of double transplantation for patients with high-risk cytogenetics and the EHA-EMN guidelines have added patients who receive VCD induction ^{13,14}.

In conclusion, our national analysis of transplant-eligible NDMM patients confirms high effectiveness (mPFS 35.5 months) and out-standing safety (TRM 0,7%) of the procedure with long-term survival (mOS 97 months). Maintenance therapy post HDT/ASCT has a beneficial effect on PFS and OS. High-dose therapy with autologous stem cell transplantation remains the cornerstone of treatment for eligible patients even in the rapidly evolving era of modern therapy. Nevertheless, the outcomes of cellular therapy in early management of the disease (CARTITUDE-5, KarMMa-4) are eagerly awaited. In the light of the deep and durable responses achieved by CAR-T therapy in relapsed setting, it may potentially supplant HDT/ASCT in first line.

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Tables

Table 1 **Baseline characteristics of the study cohort.**

(CHT chemotherapy (cyclophosphamide, doxorubicin, idarubicin, melphalan, vincristine, 2-chlordeoxyadenosin); GC glucocorticoid (dexamethasone, methylprednisolone, prednisone); IMiD immunomodulatory drug (lenalidomide, thalidomide); PI proteasome inhibitor (bortezomib, carfilzomib); * threshold 5%; ** del(17p) and/or t(4;14) and/or t(14;16)

<i>Age at diagnosis (median (95% CI))</i>	59.0 (42.0–68.0)
Sex	n = 2,149
male	1,196 (55.7%)
female	953 (44.3%)
<i>Durie-Salmon stage</i>	n = 2,116
I	304 (14.4%)
II	374 (17.7%)
III	1,438 (68.0%)
<i>Durie-Salmon subclassification</i>	n = 2,117
A	1,785 (84.3%)
B	332 (15.7%)
<i>ISS stage</i>	n = 2,043
1	911 (44.6%)
2	637 (31.2%)
3	495 (24.2%)
<i>ECOG</i>	n = 2,087
0	512 (24.5%)
1	1,166 (55.9%)
2	298 (14.3%)
3	89 (4.3%)
4	22 (1.1%)
<i>FISH</i>	
t(4;14)	n=858
negative	719 (83.8%)
positive	139 (16.2%)
t(14;16)	n=709
negative	688 (97.0%)
positive	21 (3.0%)
del(17p)*	n=884
negative	775 (87.7%)
positive	109 (12.3%)
t(11;14)	n=759
negative	636 (83.8%)
positive	123 (16.2%)
amp1q21	n=935
negative	561 (60.0%)
positive	374 (40.0%)
<i>Risk status by cytogenetics</i>	n=746
high**	243 (32.6%)
standard	503 (67.4%)
<i>Induction treatment</i>	n = 2,149

PI + IMiD + GC	631 (29.4%)
PI + GC + CHT	525 (24.4%)
GC + CHT	486 (22.6%)
IMiD + GC + CHT	336 (15.6%)
PI + GC	47 (2.2%)
PI + IMiD + GC + CHT	42 (2.0%)
others	72 (3.4%)
not specified	10 (0.5%)
<i>Dose of melphalan</i>	n = 1,730
200mg/m2	1,460 (84.4%)
140mg/m2	183 (10.6%)
100mg/m2	83 (4.8%)
other	4 (0.2%)
<i>Transplantation technique</i>	n = 2,149
single	1,881 (87.5%)
tandem	268 (12.5%)
<i>Consolidation/ maintenance</i>	n = 2,149
Consolidation	73 (3.4%)
maintenance	363 (16.9%)
lenalidomide	159 (7.4%)
other	204 (9.5%)
<i>Clinical study</i>	n = 2,149
yes	198 (9.2%)
no	1,951 (90.8%)

0 Figure Legends

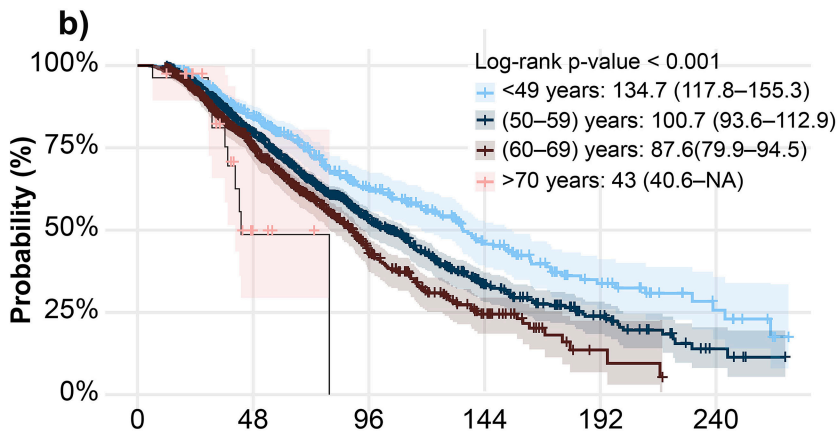
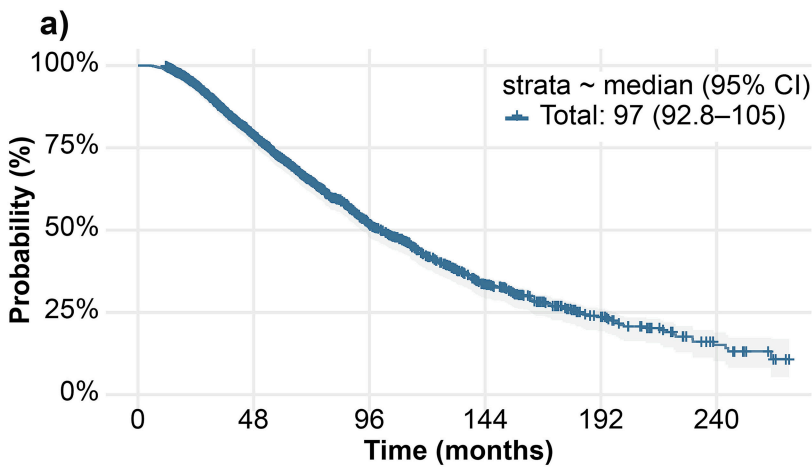
1 Figure 1: **Overall survival**

2 **(a)** Overall survival of the whole cohort; **(b)** Overall survival by age <49, (50–59), (60–69),
3 >70 at diagnosis; **(c)** Overall survival by age (60–64), (65–69) at diagnosis; **(d)** Overall
4 survival by response at day +100; **(e)** Overall survival by transplantation technique; **(f)** Overall
5 survival by the use of maintenance

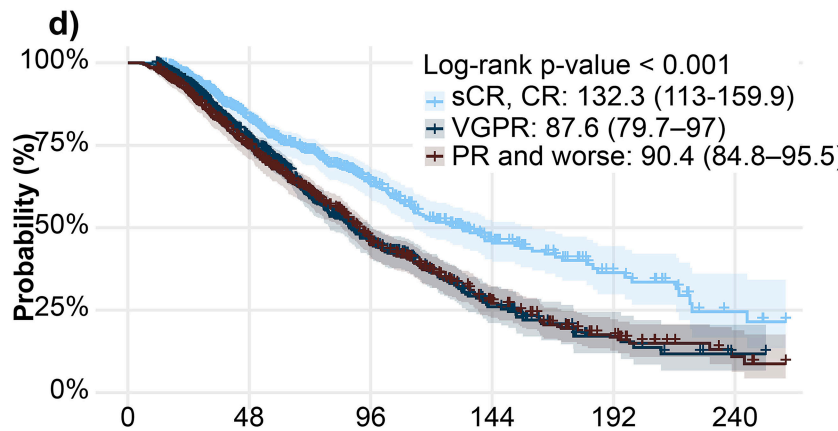
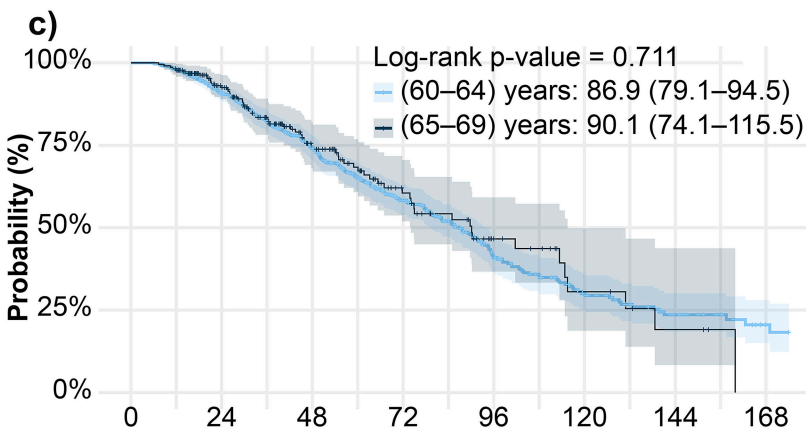
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7 Figure 2: **Progression-free survival**

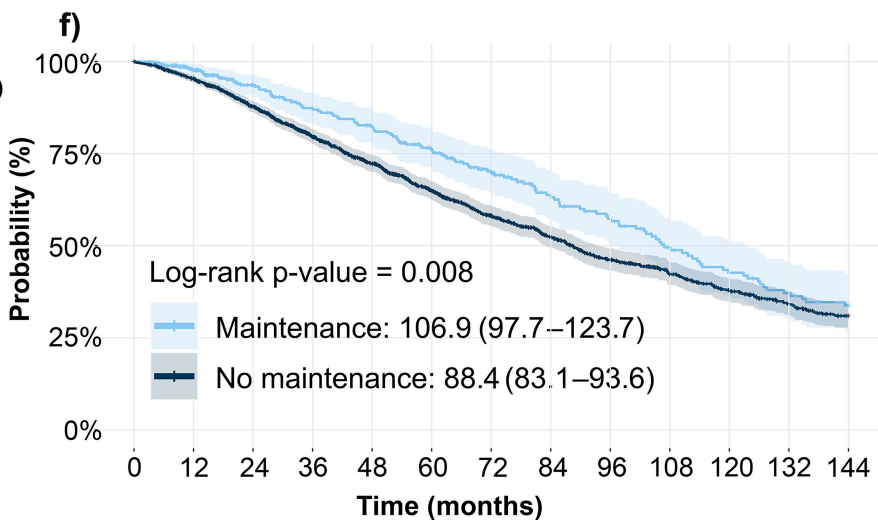
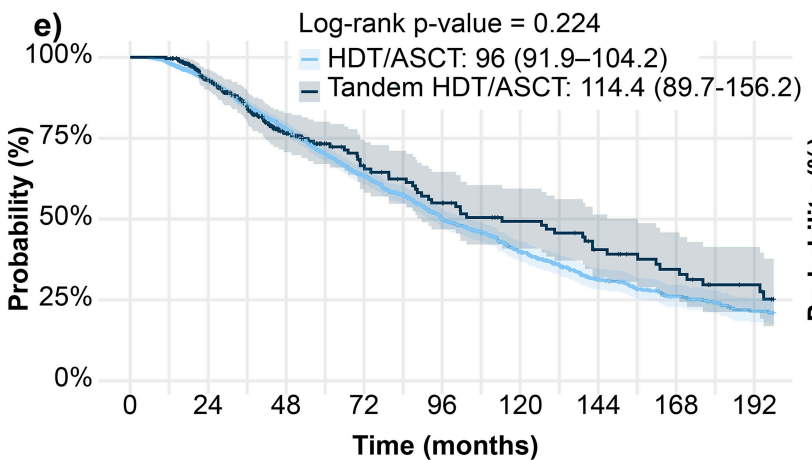
8 **(a)** Progression-free survival of the whole cohort; **(b)** Progression-free survival by age at
9 diagnosis; **(c)** Progression-free survival by response at day +100; **(d)** Progression-free
10 survival by transplantation technique; **(e)** Progression-free survival of patients with high
11 cytogenetic risk by transplantation technique; **(f)** Progression-free survival by the use of
12 maintenance



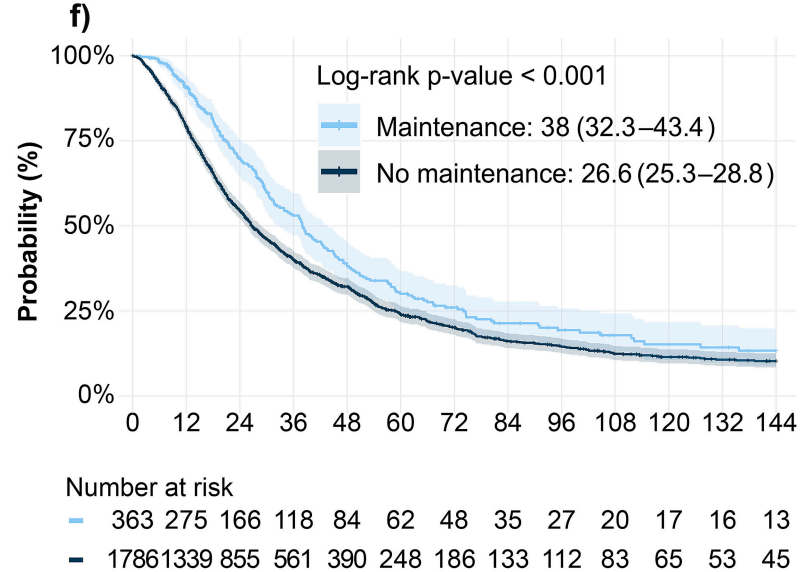
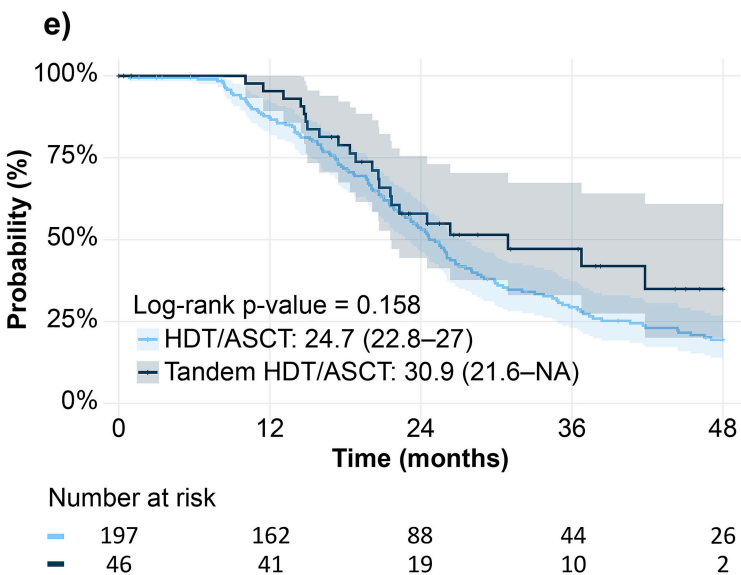
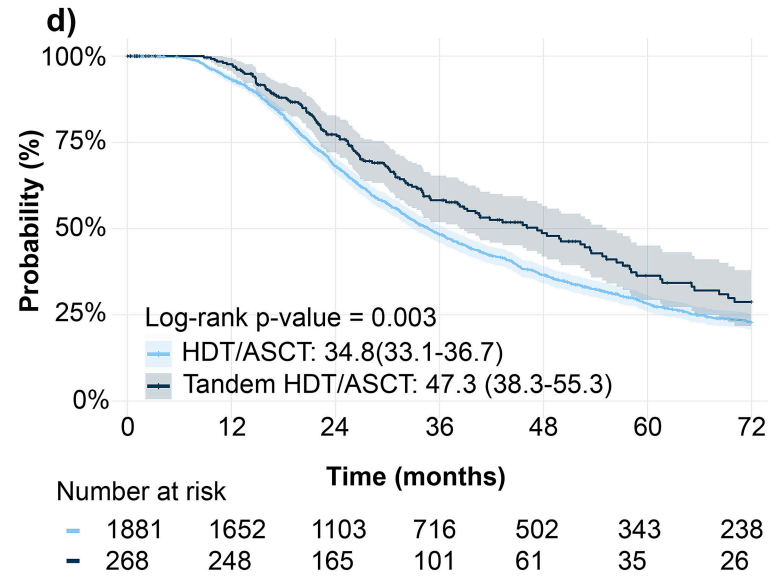
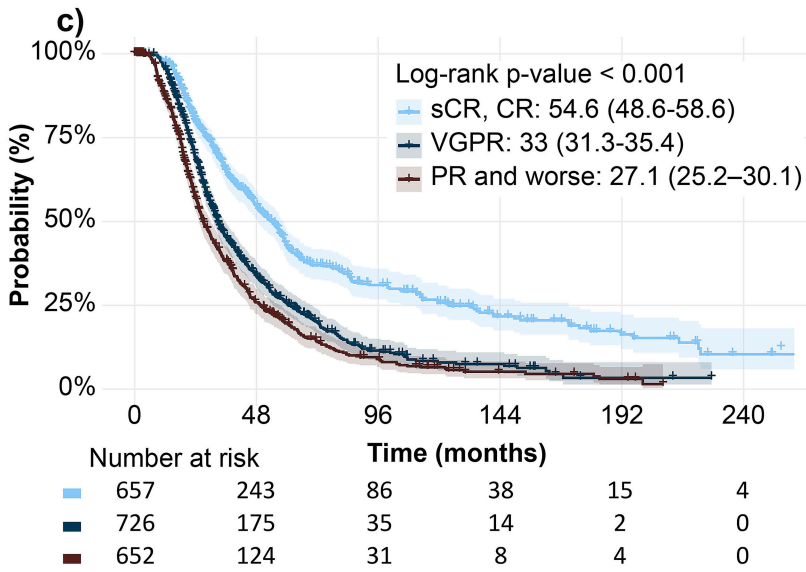
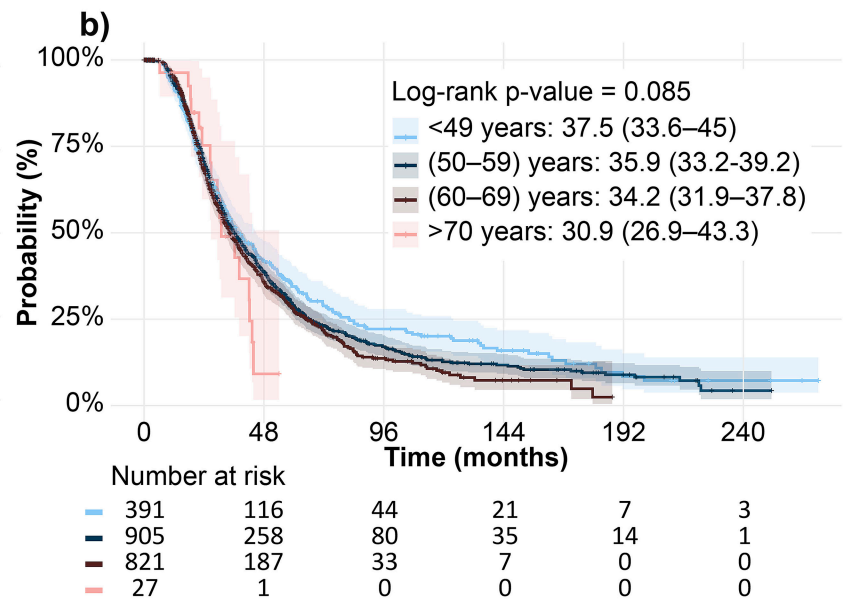
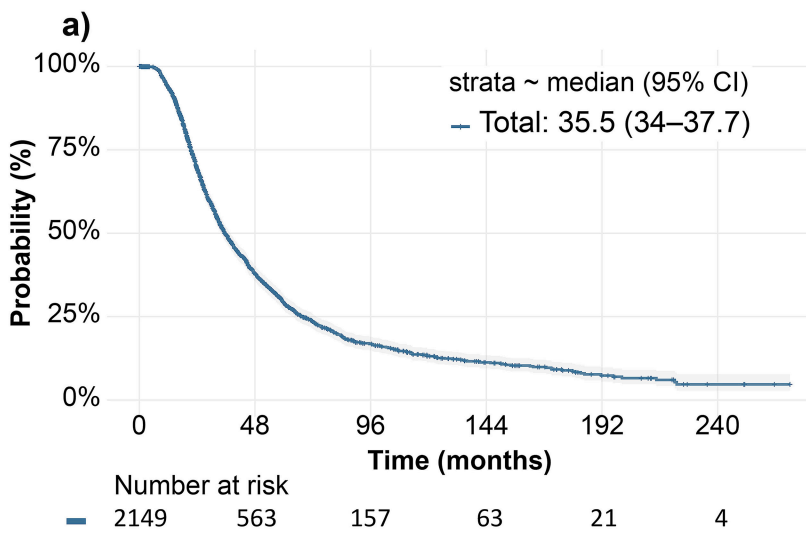
Number at risk	Time (months)					
	0	48	96	144	192	240
<49 years	391	256	129	67	27	9
(50–59) years	905	565	240	82	31	5
(60–69) years	821	422	114	29	3	0
>70 years	27	4	0	0	0	0



Number at risk	Time (months)					
	0	48	96	144	192	240
sCR, CR	657	387	169	69	26	8
VGPR	726	407	134	37	10	1
PR and worse	652	395	162	65	23	5

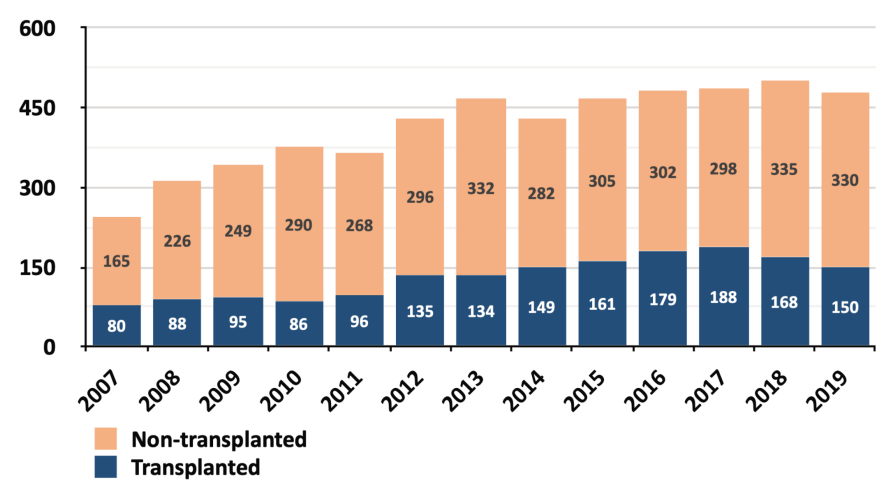


Number at risk	Time (months)													
	0	12	24	36	48	60	72	84	96	108	120	132	144	
Maintenance	363	299	231	206	190	164	131	101	85	66	55	46	38	
No maintenance	1786	1653	1416	1139	923	716	563	444	348	270	214	162	123	

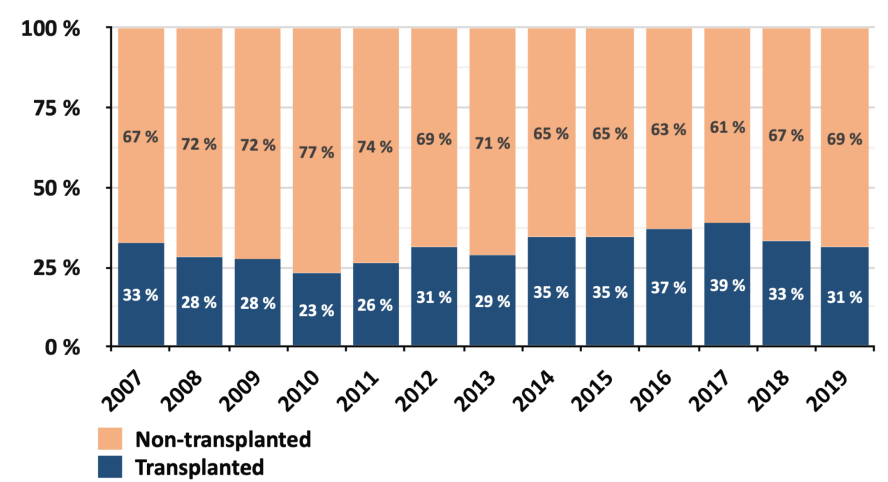


Supplementary Figure 1: **HDT/ASCT used in newly diagnosed MM patients between 2007-2019 (a) in absolute numbers; (b) proportionally.**

a)



b)



Supplementary Table 1: **Multivariable Cox proportional hazard model for OS and PFS**

	number of patients	OS		PFS	
		HR (95% CI)	p-value	HR (95% CI)	p-value
Cytogenetic risk at diagnosis					
standard risk – reference	491	–	–	–	–
high risk	234	2.23 (1.74–2.86)	2.54E-10	1.73 (1.41–2.11)	8.01E-08
Age at diagnosis					
<49 years – reference	113	–	–	–	–
(50–59) years	272	1.37 (0.94–2.01)	0.1032	1.29 (0.97–1.73)	0.0788
> 60 years	340	1.61 (1.10–2.36)	0.0146	1.41 (1.05–1.88)	0.0214
ISS at diagnosis					
stage 1 – reference	282	–	–	–	–
stage 2	258	1.08 (0.80–1.46)	0.6007	0.94 (0.75–1.18)	0.5889
stage 3	185	1.31 (0.95–1.82)	0.104	1.09 (0.85–1.40)	0.4997
DS at diagnosis					
stage I – reference	92	–	–	–	–
stage II	118	1.08 (0.66–1.77)	0.7586	1.30 (0.90–1.87)	0.1656
stage III	515	1.42 (0.94–2.15)	0.099	1.62 (1.19–2.22)	0.0026
ECOG at diagnosis					
grade 0 – reference	183	–	–	–	–
grade 1	395	1.34 (0.97–1.83)	0.0745	0.96 (0.76–1.20)	0.7064
grade 2	108	1.46 (0.96–2.22)	0.0801	1.02 (0.74–1.40)	0.8893
grade ≥3	39	1.34 (0.73–2.45)	0.3448	1.23 (0.80–1.90)	0.3484

Supplementary Table 2: **Univariate analysis for OS and PFS.** **del(17p) and/or t(4;14) and/or t(14;16)

	number of patients	OS			PFS		
		median (months)	95% CI	p-value	median (months)	95% CI	p-value
<i>Whole cohort</i>	2 149	97.0	(92.8-105.0)		35.5	(34.0-37.7)	
<i>Age</i>							
<49 years	391	134.7	(117.8–155.3)		37.5	(33.6–45.0)	
(50–59) years	905	100.7	(93.6–112.9)		35.9	(33.2–39.2)	
(60–69) years	821	87.6	(79.9–94.5)		34.2	(31.9–37.8)	
>70 years	27	43.0	(40.6–NA)	<0.001	30.9	(26.9–43.3)	0.088
(60–64) years	599	86.9	(79.1–94.5)		34.0	(31.4–37.7)	
(65–69) years	222	90.1	(74.1–115.5)	0.711	35.4	(31.7–44.7)	0.547
<i>Risk stratification by FISH</i>							
standard	503	100.7	(89.7–134.6)		36.7	(33.5–39.5)	
high**	243	60.8	(51.6–73.3)	<0.001	25.4	(23.2–28.0)	<0.001
<i>amp1q21</i>							
negative	561	100.7	(87.2–113.4)		38.1	(34.1–42.1)	
positive	374	67.4	(58.4–74.1)	<0.001	26.3	(24.5–29.8)	<0.001
<i>t(11;14)</i>							
negative	636	95.5	(85.5–105.3)		35.8	(33.6–39.0)	
positive	123	96.2	(79.2–138.3)	0.784	33.3	(29.8–50.0)	0.565
<i>Response after transplantation</i>							
≥CR	657	132.3	(113.0–159.9)		54.6	(48.6–58.6)	
VGPR	726	87.6	(79.7–97.0)		33.0	(31.3–35.4)	
≤PR	652	90.4	(84.8–95.5)	<0.001	27.1	(25.2–30.1)	<0.001
<i>Transplantation technique</i>							
single	1 881	96.0	(91.9–104.2)		34.8	(33.0–36.7)	
tandem	268	114.4	(89.7–156.2)	0.224	47.3	(38.3–55.2)	0.024
<i>Transplantation technique at standard cytogenetic risk</i>							

single	415	105.3	(86.6–135.3)		36.3	(32.6–39.7)	
tandem	88	92.8	(70.8–NA)	0.466	38.3	(33.4–52.8)	0.425
<i>Transplantation technique at high cytogenetic risk</i>							
single	197	61.9	(51.8–75.7)		24.7	(22.8–27.0)	
tandem	46	101.6	(35.2–NA)	0.384	30.9	(21.6–NA)	0.158