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**47° Congress of the Italian Society of Hematology
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The origin of a name that reflects Europe's cultural roots.

Ancient Greek

αἷμα [haima] = blood
αἷματος [haimatos] = of blood
λόγος [logos] = reasoning

Scientific Latin

haematologicus (adjective) = related to blood

Scientific Latin

haematologica (adjective, plural and neuter,
used as a noun) = hematological subjects

Modern English

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KRd_ASCT_KRd vs KRd12 (12 patients [8%] vs 26 patients [17%]; $p=0.015$), mainly related to a significantly lower rate of early relapse in high-risk patients (R-ISS Stage 2/3) (11 patients [12%] vs 22 patients [23%]; $p=0.05$, respectively). Very few patients with R-ISS Stage 1 relapsed, with no difference between KRd_ASCT_KRd and KRd12 (0 vs 2 patients). In multivariate regression analysis, patients receiving KRd_ASCT_KRd had a reduced risk of early relapse vs those treated with KRd12 (OR 0.42; $p=0.021$); R-ISS Stage 2 (OR 3.6; $p=0.001$) and R-ISS Stage 3 (OR 4.85; $p=0.003$) increased the risk of early relapse vs R-ISS 1.

Conclusions: KRd-ASCT-KRd and KRd12 were equally effective in inducing high-quality responses, and ~50% of high-risk patients achieved MRD negativity. In addition, ASCT was beneficial in high-risk patients, reducing the risk of early relapse.

Table 1.

	Table 1A: Overall population		Table 1B: Subgroup analysis			
	KRd_ASCT_KRd	KRd12	R-ISS 1		R-ISS 2/3	
	N=158	N=157	KRd_ASCT_KRd N=48	KRd12 N=39	KRd_ASCT_KRd N=92	KRd12 N=94
≥CR	44%	43%	46%	49%	39%	38%
≥VGPR	60%	61%	60%	64%	56%	57%
MRD negative	89%	87%	92%	79%	86%	86%
MRD positive	58%	54%	69%	62%	51%	47%

B005

SECOND PRIMARY MALIGNANCY IN MYELOFIBROSIS PATIENTS TREATED WITH RUXOLITINIB

N. Polverelli, E. Elli, E. Abruzzese, G.A. Palumbo, G. Benevolo, M. Breccia, M. Tiribelli, M. Bonifacio, A. Tieghi, B. Martino, N. Sgherza, M. D'Adda, M. Bergamaschi, M. Crugnola, F. Cavazzini, C. Bosi, G. Binotto, A. Isidori, D. Bartoletti, G. Auteri, R. Latagliata, L. Gandolfi, L. Scaffidi, D. Cattaneo, K. Codeluppi, M. Trawinska, D. Griguolo, A. Cuneo, M. Krampera, G. Semenzato, F. Di Raimondo, R.M. Lemoli, M. Cavo, N. Vianelli, D. Russo, A. Iurlo, F. Palandri

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Ruxolitinib (RUX), the first JAK1/JAK2 inhibitor approved for myelofibrosis (MF) therapy, has been recently associated with the occurrence of second primary malignancies (SPMs), mainly lymphoid neoplasms and non-melanoma skin cancers (NMSCs). Herein, we analyzed incidence and risk factors of SPMs in 589 MF pts treated with RUX in 20 European Hematology Centers. Cumulative incidence of SPMs was calculated according to Fine and Gray model with death without SPM as competitive event. Uni and multivariate analysis were carried out by Fine-Gray proportion hazard regression for competing risks. The char-

acteristics of the MF cohort were the following: median age 65y (15-88); male gender 58%; PMF 51%; JAK2, CALR and MPL mutation 83%, 11% and 2% of 530 evaluable pts; median RUX exposure 36 mos (1-86), prior cytoreduction use in 362 pts (HU 98%), previous neoplasms in 40 pts (43 events).

Seventy pts (12%) developed 74 SPMs after RUX start, with a cumulative incidence of 2.3%, 4.5% and 14.3% at 1, 2 and 5y, respectively. Incidence rate of SPMs was 3.91 100 pts/y. Clinical features were comparable between pts with or without SPMs. NMSCs were the most common SPMs accounting for 38 events in 34 pts, other neoplasms involved urological district (13), lung (9), GI tract (6), hematopoietic tissue (2, 1 CML and 1 Langerhans cell histiocytosis), others (6). In 17 out of 213 deceased pts (8%), SPM was the ultimate cause of death. SPM diagnosis did not affect OS, even after excluding NMSC, with projected survival of 81 and 84% at 2y for pts with or without SPM ($p=0.96$). By univariate analysis, age at RUX start >55y ($p=0.035$), CALR mutation ($p=0.023$), HU time-exposure ($p=0.003$) and male sex ($p<0.001$) were associated with increased incidence of SPMs; in multivariate analysis, CALR mutation, HU use and sex maintained statistical significance (HR 3.78, CI95% 1.61-8.87 $p=0.002$, HR 1.07, CI95% 1.02-1.13 $p=0.01$ and HR 2.63, CI95% 1.08-6.43, $p=0.034$ respectively). After exclusion of NMSCs, HU lost any statistical significance (HR 1.01, CI95% 0.94-1.08); on the contrary, mutational status and sex confirmed their prognostic value (HR 2.99, CI95% 1.28-7.02 $p=0.011$ and HR 2.67, CI95% 1.17-6.09 $p=0.019$, respectively). Notably, RUX time-exposure, and starting/cumulative dose were not associated with SPMs. In conclusion, mutational status and male sex represent the major predictive factors for SPMs occurrence in RUX-treated pts. HU time-exposure was strongly associated with NMSCs.

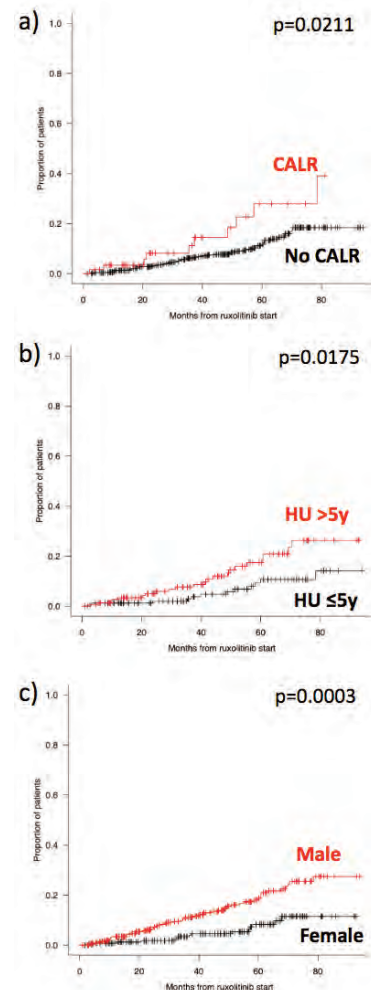


Figure 1. Cumulative incidence of SPMs according presence of CALR mutation (a), HU exposure >5y (b) and male sex (c).