

099. RISK OF DEVELOPING A FIRST INVASIVE MELANOMA IN RHEUMATOID ARTHRITIS PATIENTS TREATED WITH BIOLOGICS: RESULTS OF A COLLABORATIVE PROJECT OF 11 EUROPEAN BIOLOGICS REGISTERS

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Background: Swedish and Danish national biologics registers have reported a possible increase in melanoma risk with TNF inhibitors. As melanomas are uncommon, the association is difficult to evaluate in other individual registers. We therefore planned a EULAR collaborative project.

Methods: Patients with RA from 11 European biologics registers in 9 countries were included. Patients were followed prospectively from start of a new biologic treatment until the occurrence of first invasive histology-confirmed cutaneous melanoma, using an ever-exposed approach. For the TNFi cohort, prior exposure to biologic drugs was not permitted. Prior exposure to TNFi was allowed for other biologic drugs. For each register, incidence rates and standardized incidence ratios (SIR) of melanoma were calculated by using age-, sex- and calendar year-specific rates from the general population of the corresponding country as reference. Poisson regression models were used to summarize the register-specific SIRs to overall SIR estimates. Rates of melanoma in biologic exposed patients were compared with those in biologic-naïve patients enrolled in participating registers by calculating incidence rate ratios (IRRs). Overall SIRs and IRRs were calculated, taking the size of the registers into account.

Results: Overall, 114 291 patients were available for analysis: mean age 58 years; 74% female. 287 developed a first invasive melanoma. Background population rates varied due to differences in the incidence by country, calendar years and differences in the age and sex distribution of the corresponding RA cohorts (Table 1). The SIRs for biologic naïve patients were similar across the registers whereas there was variation in SIRs between TNFi cohorts (Table 1). The overall IRRs

did not show a significantly increased melanoma risk for any of the biologic therapies compared with biologic-naïve patients.

Conclusion: This large European collaborative project of 11 registers from 9 countries did not confirm an increased risk of melanoma following exposure to TNFi, although an association cannot be completely ruled out with these data.

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099 TABLE 1. Melanomas, standardized incidence ratios and incidence rate ratios in RA treatment cohorts

		Person-years	Population rate, per 100 000	Observed	Expected	SIR (95% CI)	IRR (95% CI)
Biologic naïve	Total	300011	48	160	144.3	1.1 (0.9, 1.4)	Referent
	ARTIS	222496	52	133	115.5	1.2 (1.0, 1.4)	Referent (ARTIS)
	BSRBR	22972	35	9	8.0	1.1 (0.5, 2.1)	Referent (BSRBR)
	DANBIO	27469	57	14	15.7	0.9 (0.5, 1.5)	Referent (DANBIO)
	RABBIT	9916	33	4	3.3	1.2 (0.3, 3.1)	Referent (RABBIT)
TNF	Total	242814	35	106	85.5	1.2 (1.0, 1.6)	1.1 (0.8, 1.6)
	ARTIS	59166	44	39	26.0	1.5 (1.1, 2.1)	1.3 (0.9, 1.9)
	BSRBR	90259	31	31	28.1	1.1 (0.8, 1.6)	1.0 (0.5, 2.3)
	DANBIO	22972	49	18	11.3	1.6 (0.9, 2.5)	1.8 (0.8, 3.9)
	RABBIT	23103	31	7	7.1	1.0 (0.4, 2.0)	0.8 (0.2, 3.8)
	GISEA	16180	40	6	6.4	0.9 (0.3, 2.0)	
	SCQM	15605	26	3	4.1	0.7 (0.2, 2.2)	
	ATTRA	8441	22	1	1.8	0.6 (0.0, 3.0)	
	Rheuma.pt	7088	9	1	0.7	1.5 (0.0, 8.3)	
	Rituximab	Total	29619	35	13	10.3	1.3 (0.6, 2.5)
Tocilizumab	Total	5798	33	5	1.9	2.7 (0.8, 8.4)	2.4 (0.6, 10.1)
Abatacept	Total	4858	29	2	1.4	1.5 (0.1, 30.9)	1.3 (0.2, 7.6)